EXHIBIT 2

State Court Pleadings - Part One

2019CP4004521 : State Of South Carolina , plaintiff, et al vs Mckesson Corporation , defendant, et al

Common Pleas

Case Number 2019CP4004521
Case Subtype Unfair Trade Pra 640
Filed Date 08-15-2019
Status Pending/ADR

Plaintiff State Of South Carolina et al
Defendant Mckesson Corporation et al
Assigned Judge Clerk Of Court C P, G S, And Family Court
File Type Jury

Show/Hide Participants

Name	Description	Type	File Date
State Of South Carolina	ADR/Alternative Dispute Resolution (Workflow)	Action	03-12-2020 12:55:22 PM
Amerisourcebergen Drug Corporation	NEF(09-17-2019 02:54:38 PM) Order/Consent Order	Filing	09-17-2019 02:54:45 PM
Amerisourcebergen Drug Corporation	Order/Consent Order	Order	09-17-2019 02:54:38 PM
Amerisourcebergen Drug Corporation	NEF(09-17-2019 12:10:45 PM) Proposed Order/Consent Order	Filing	09-17-2019 02:24:46 PM
Amerisourcebergen Drug Corporation	NEF(09-17-2019 12:28:40 PM) Notice/Notice of Appearance	Filing	09-17-2019 12:28:53 PM
Amerisourcebergen Drug Corporation	Notice/Notice of Appearance	Filing	09-17-2019 12:28:40 PM
Amerisourcebergen Drug Corporation	Order/Order Cover Sheet $25.00	Filing	09-17-2019 12:10:45 PM
Amerisourcebergen Drug Corporation	NEF(09-17-2019 11:51:08 AM) Notice/Notice of Appearance	Filing	09-17-2019 11:51:24 AM
Amerisourcebergen Drug Corporation	Notice/Notice of Appearance	Filing	09-17-2019 11:51:08 AM
State Of South Carolina	NEF(09-09-2019 12:24:35 PM) Letter/Letter	Filing	09-09-2019 12:24:44 PM
State Of South Carolina	Letter for Addmission Pro Hac Vice for Linda Singer	Filing	09-09-2019 12:24:35 PM
State Of South Carolina	NEF(08-16-2019 03:55:12 PM) Motion/Other	Filing	08-16-2019 04:10:48 PM
State Of South Carolina	Motion To Provisionally File Unredacted Appendix To The Comp	Motion	08-16-2019 03:55:12 PM
State Of South Carolina	Motion To Provisionally File Unredacted Appendix To The Comp	Motion	08-16-2019 03:55:12 PM
State Of South Carolina	Motion To Provisionally File Unredacted Appendix To The Comp	Motion	08-16-2019 03:55:12 PM
State Of South Carolina	Summons & Complaint	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_1	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_2	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_3	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_4	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_5	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_6	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_7	Filing	08-15-2019 12:55:22 PM
State Of South Carolina	Summons & Complaint-EX_8	Filing	08-15-2019 12:55:22 PM

STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	
COUNTY OF RICHLAND)	FIFTH JUDICIAL CIRCUIT
THE STATE OF SOUTH CAROLINA, ex rel. Alan Wilson, in his official capacity as Attorney General of the State of South Carolina, Plaintiff, vs. McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation. Defendants.	Civil Action No.: **SUMMONS**

To: Counsel for the Defendants:

YOU ARE HEREBY SUMMONED and required to answer the Complaint in this action, a copy of which is herewith served upon you, and to serve a copy of your Answer to the Complaint on the subscriber at his office, South Carolina Attorney General's Office, P.O. Box 11549, Columbia, South Carolina 29211, within thirty (30) days after the service hereof, exclusive of the day of such service, and if you fail to answer the Complaint with in the time aforesaid, the Plaintiff in this action will apply to the Court for the relief demanded in the Complaint.

DATED: August 15, 2019.

/s/ Alan Wilson
Alan Wilson
Attorney General
Attorney for Plaintiff

STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	
COUNTY OF RICHLAND)	FIFTH JUDICIAL CIRCUIT
THE STATE OF SOUTH CAROLINA, ex rel. Alan Wilson, in his official capacity as Attorney General of the State of South Carolina, Plaintiff, vs.)	Civil Action No.:
McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation. Defendants.)	**Complaint** **Jury Trial Requested**

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF UNDER SOUTH CAROLINA'S CONSUMER PROTECTION AND COMMON LAWS.

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INTRODUCTION

1. The Attorney General brings this action pursuant to his *parens patriae*, constitutional, statutory, and common law authority, including the authority granted to him by the South Carolina Unfair Trade Practices Act, S.C. Code §§ 39-5-20, 50 and 110 ("SCUTPA") to redress the unfettered and unlawful distribution of opioids by Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal"), and AmerisourceBergen Drug Corporation ("AmerisourceBergen") (collectively, "Defendants'), and to abate the public nuisance Defendants helped create.

2. This case is part of the State's ongoing effort to combat the worst human-made epidemic in modern medical history—the overuse, misuse, and abuse of opioids. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control ("CDC"), "I don't think we've ever seen anything like this. Certainly not in modern times."[1] South Carolina is now swept up in what the CDC called a "public health epidemic" and what the U.S. Surgeon General deemed an "urgent health crisis."[2]

3. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak.

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[1] Associated Press, *Drug Overdoses Killed 50,000 in U.S., More than Car Crashes*, (Dec. 9, 2016), https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001

[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at *http://turnthetiderx.org*.

4. The outcomes in South Carolina are catastrophic—and getting worse. As of January 2018, combined heroin and prescription opioid overdose deaths in South Carolina had exceeded the number of homicides in the state for three straight years. In 2017, Governor Henry McMaster declared South Carolina's opioid epidemic a public health emergency, describing the epidemic as a "silent hurricane."[3] The same year, South Carolina saw 748 fatal overdoses, a 21% increase from the number of lives lost in 2016. This was the third straight year that deaths from opioid-related overdoses increased in the state, and there has been a 47% percent increase in overdose deaths since 2014.

5. South Carolina stands out even amidst a national epidemic. Heroin overdoses in the state increased by 57% from 2014 to 2015 — the largest percentage increase in any state during that time period — the result of patients who could not get access to prescription opioids and turned to heroin. In 2017 alone, 144 people in South Carolina lost their lives to heroin overdoses, and in 2018, the number of lives lost grew to 168.

6. From 2013 to 2016, as the epidemic grew, the number of attempts to reverse opioid overdoses by EMS personnel throughout South Carolina increased by 67%. In 2017 alone, South Carolina emergency and inpatient departments treated and discharged more than 10,700 people suffering from issues related to opioid use or dependence. Although the most recent data was not yet available, the Director of the South Carolina Department of Alcohol and Other Drug Abuse Services commented in March 2018: "I'm afraid of what it's going to say and how heavy it's going

[3] Gavin Jackson, McMaster Declares Public Health Emergency Over Opioid Epidemic, etv (Dec. 18, 2017), *https://www.scetv.org/stories/week-south-carolina/2017/mcmaster-declares-public-health-emergency-over-opioid-epidemic?page=&ref=stories/tags/opioids*.

to feel when this is perhaps the biggest killer in our state."[4] And, in just the first six months of 2019, opioids have been blamed for 46 deaths in Charleston County alone. Fears about the number of lives lost in 2018 proved justified when, in August 2019, the South Carolina Department of Environmental Control ("DHEC") released a report showing that 816 people in South Carolina died of opioid overdoses last year.

7. Meanwhile, recently disclosed information about the distribution of opioids into South Carolina also has sounded alarms. The federal Drug Enforcement Administration ("DEA") maintains a system of records, known as the "Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)," to which all manufacturers and distributors of controlled substances are required to report each transaction in these drugs. The manufacturers and distributors have typically opposed disclosure of the information contained in the system, often referred to as "ARCOS data," arguing that it belongs to them as trade secrets. Recently, journalists challenged their claims of secrecy, and a federal appellate court ordered the release of nationwide ARCOS data for the years 2006 to 2014, which the DEA had produced in federal multi-district litigation arising out of the opioid epidemic, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio) (the "MDL"). Although that dispute remains ongoing, the MDL Court has determined that there was "clearly no basis to shield from public view ARCOS data dated on or before December 31, 2012," paving the way for its release. *See* Order Regarding ARCOS Data Protective Order, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio July 15, 2019) (data from 2013-2014 was not publically released). Based on this information,

[4] Daniel J. Gross, *Opioid Crisis Not Letting Up in Greenville County*, (Mar. 11, 2018, updated Mar. 12, 2018), *https://www.greenvilleonline.com/story/news/crime/2018/03/11/opioid-overdoses-south-carolina/391706002/*.

the *Washington Post* reported that during 2006-2012 South Carolina received the third highest concentration of pills per person per year of any state in the nation.[5]

8. The same data also revealed that "Charleston County had the highest average distribution rate of pain pills per person per year of any county in the United States from 2006 through 2012."[6] Between those years, an average of **248.3 pills per person per year** were distributed in Charleston County.[7]

9. Defendants McKesson, Cardinal, and AmerisourceBergen played an outsized role in flooding South Carolina with these drugs. Known colloquially as the "Big Three," Defendants dominate the wholesale drug distribution market nationally, and these three companies were responsible for more than half the opioids shipped into South Carolina from 2006 to 2014, the period for which the State has obtained ARCOS data.

10. Distributors McKesson, Cardinal, and AmerisourceBergen buy prescription drugs, including narcotics, from manufacturers at enormous volumes and sell them to pharmacies. This allows pharmacies to quickly obtain a full range of prescription drugs from a single source, without having to manage relationships with multiple manufacturers. With distribution centers across the country, Defendants offer "just-in-time delivery," ensuring that pharmacies can provide the drugs their customers need, without the expense and risk of excess inventory. Like other brokers,

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[5] Scott Higham, Sari Horwitz, and Steven Rich, *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, The Washington Post (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html?utm_term=.fb8463a9e736.

[6] Live 5 News – Newly Released DEA Data Shows High Opioid Distribution Rate in Charleston Co., https://www.live5news.com/2019/07/17/newly-released-dea-data-shows-high-opioid-distribution-rate-charleston-co/.

[7] *Id.*

distributors earn their profits based on the spread between their buy and sell prices, as well as manufacturer chargebacks and a fee that is a percentage of sales.[8] As discussed further below, they have financial incentives to keep their volumes high. With their central location in the healthcare marketplace, they also have a treasure trove of information, which they use to further leverage their profits, selling data and services upstream to manufacturers and downstream to pharmacies. They could have used this information to ensure they were providing opioids only to a legitimate market, but did not.

11. Distributors have an obligation under SCUTPA, the South Carolina Controlled Substances Act, S.C. Code § 44-53-10 *et seq.* ("SCCSA"), the federal Controlled Substances Act, U.S. Code 21 U.S.C. § 801 *et seq.* ("CSA"), and South Carolina common law to ensure that they safely hold and distribute all of the prescription drugs for which they are responsible. That duty is nowhere more important than with controlled substances, like opioids. Because of the addictive nature of these drugs and the existence of a black market for their use, distributors have a long-standing duty under South Carolina and federal law, as described further below, to ensure that the controlled substances they supply, including opioids, are managed and monitored to ensure they reach only a legitimate market and are not diverted for illicit use.

12. Over a critical decade, as orders for opioids skyrocketed, Defendants failed to comply with SCUTPA, the SCCSA, the CSA, and their common law duty of reasonable care. Defendants oversupplied opioids into and within South Carolina, and ignored obvious red flags of

[8] Because manufacturers typically negotiate sales prices directly with large buyers, a distributor might initially lose money when it sells prescription drugs to a buyer at a lower, discounted price than its purchase price. The distributor then bills the manufacturer for the difference between the price it paid and the negotiated price, a payment known as a "chargeback." *See* Coleman, John, *The Supply Chain of Medicinal Controlled Substances: Addressing the Achilles Heel of Drug Diversion,* Journal of Pain & Palliative Care Pharmacotherapy, Sept. 13, 2012, at p. 240.

diversion. The ARCOS data described above shows that together, Defendants distributed the equivalent, at 10 mg per pill,[9] of nearly 2.2 billion opioid pills into South Carolina between 2006 and 2014—nearly 500 times the state's population of roughly 4.6 million residents at the time. Cardinal shipped 24.99% of this volume of estimated 10 mg pills into the State, McKesson 20.38%, and AmerisourceBergen 8.42%, over that time.

13. In response to enforcement actions and public attention, Defendants finally began to improve their compliance efforts in an attempt to meet their legal obligations, but the opioid epidemic was already well underway. Defendants have shipped opioids at alarming volumes and doses into South Carolina for years. Defendants have failed to comply with their obligations to maintain effective systems to guard against diversion, and failed to report suspicious orders to law enforcement as required. Defendants conduct in violation of their statutory obligations and common law duties has fueled and enabled the rising tide of opioid overuse, abuse, addiction, overdose, and death.

14. Further, although ARCOS data is not currently publicly available from 2015 forward, more recent information, including that unveiled through a DEA enforcement action that resulted in a record-breaking fine against McKesson, as well as Congressional inquiries and Defendants' own internal documents, show that Defendants did not truly reform their ways and comply with their statutory and common law duties. Instead, Defendants widespread systemic failures still continue to devastate South Carolina.

15. The State recognizes that the opioid manufacturers played a significant role in the crisis it now confronts. However, distributors assisted the manufacturers in promoting these powerful, addictive narcotics. And, had Defendants complied with their legal duties to monitor,

[9] For ease of comparing different opioid strengths, other dosages are converted into 10 mg pills.

report, and reject orders of opioids that were excessive and clearly suspicious, these pills would have been far less accessible to the patients who became addicted to them and in some cases died from them.

16. The overwhelming increase of opioids ordered by South Carolina pharmacies, collectively and individually, put Defendants on notice that they were meeting more than a predictable and legitimate market demand. Rather than continuing to sell, ship, and profit from these highly dangerous drugs, they had a duty to report and stop their diversion. Had they done so, the opioid epidemic in South Carolina—and its enormous human and financial toll—would not have been as grave.

17. The State brings this action through the Attorney General to hold Defendants responsible for their violations of law and to abate the ongoing opioid epidemic. Defendants' actions violate SCUTPA's prohibitions on unfair or deceptive acts and practices, S.C. Code §§ 39-5-20, 50, and 110. Additionally, their conduct constitutes a common law public nuisance. The State seeks injunctive relief, civil penalties, abatement, and any other relief within this Court's powers to redress and halt these unlawful practices.

II. PARTIES

A. PLAINTIFF

18. The Plaintiff State of South Carolina brings this action, by and through its Attorney General, Alan Wilson, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant to his *parens patriae*, constitutional, statutory, and common law authority, including the authority granted to him by the South Carolina Unfair Trade Practices Act, S.C. Code §§ 39-5-20, 50 and 110 and S.C. Code § 1-7-40.

B. DEFENDANTS

1. Cardinal Health, Inc.

19. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company." Through its various DEA registrant subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, in South Carolina. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio.

20. Cardinal, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of pharmaceutical drugs in South Carolina since at least 2000.

2. McKesson Corporation

21. McKesson Corporation ("McKesson"), through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids in South Carolina. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

22. McKesson, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of pharmaceutical drugs in South Carolina since at least 2001.

3. AmerisourceBergen

23. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids in South Carolina. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

24. AmerisourceBergen has been licensed as a wholesale distributor of pharmaceutical drugs in South Carolina since 2002.

25. Together, Cardinal Health, McKesson, and AmerisourceBergen, known collectively as the "Big Three," shipped more than half of the estimated 10 mg equivalent pills

distributed in South Carolina from 2006 to 2014. More recent information shows that nationally, they dominate more than 85% of the market share for the distribution of prescription opioids.

JURISDICTION AND VENUE

26. This Court has jurisdiction over the subject matter of this case pursuant to S.C. Const. Art. V. § 11, which gives the Circuit Court general jurisdiction over civil actions. This Court has personal jurisdiction over the Defendants because the Defendants do business in South Carolina and/or have the requisite minimum contacts with South Carolina necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being within the contemplation of South Carolina's "long arm" statute, S.C. Code § 36-2-803.

27. Venue is appropriate in Richland County pursuant to S.C. Code § 15-7-10, *et seq*., § 39-5-50, and § 35-1-603.

28. On May 8, 2017, the Attorney General issued notice to Defendants as required by S.C. Code § 39-5-50.

29. The claims underlying this action are brought within the requisite filing period. Based on the statutes of limitations for the claims asserted, to include claims based on SCUTPA and common law, and based on when the Attorney General knew or should have known that Defendants' conduct gave rise to these claims, the statute of limitations has not run for any claim alleged herein.

IV. FACTUAL ALLEGATIONS

A. DEFENDANTS DELIBERATELY FLOODED SOUTH CAROLINA WITH ADDICTIVE NARCOTIC PAINKILLERS, WELL BEYOND WHAT A LEGITIMATE MARKET OF SOUTH CAROLINA'S SIZE COULD BEAR.

1. Opioid Volumes Soar in South Carolina.

30. Although the pharmaceutical companies created a vastly and dangerously larger market for opioids, Defendants compounded this harm by facilitating the supply of far more

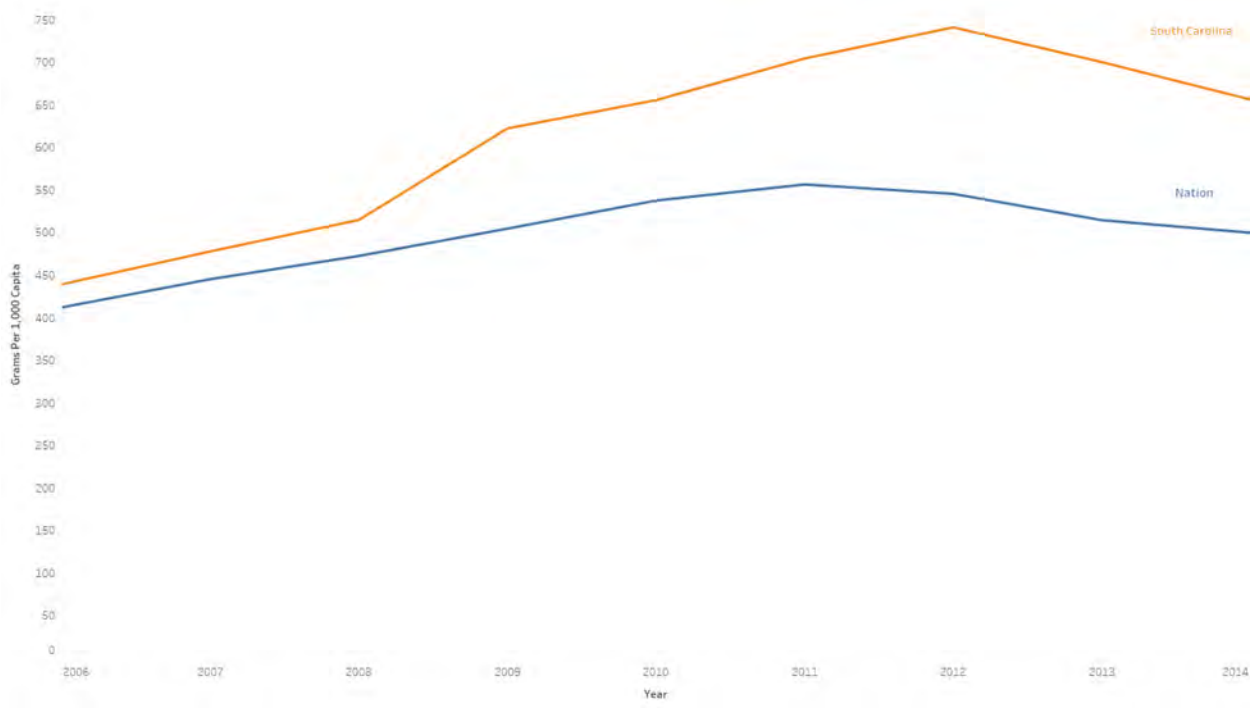
opioids than could have been justified. Their failure to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties and worsened and failed to prevent the opioid epidemic in South Carolina.

31. Together, Defendants delivered over **40%** of the more than **two billion dosage units and 50% of the 15 million grams (**equating to more than 1.7 billion estimated 10 mg equivalent pills) of opioids shipped to South Carolina retail and chain pharmacies, including over 45 million dosage units and over 520,000 grams (equating to 102 million estimated 10 mg equivalent pills) shipped to the top 15 dispensing pharmacies in the State, from 2006 to 2014.[10] The number of estimated pills per person shipped by Defendants increased over 130% from 2006-2013, from approximately 26 estimated 10 mg equivalent pills per person in 2006 to approximately 55 estimated 10 mg equivalent pills per person in 2013, the year that, based on records produced by the DEA, McKesson first reported a suspicious transaction in South Carolina.[11] The number of estimated 10 mg equivalent pills per person that they distributed increased every year from 2006 to 2014, peaking in 2014, when Defendants shipped the equivalent of over 303,000 pills to South Carolina, or approximately 62 pills per South Carolinian.

32. Throughout that time, per capita opioid prescriptions in South Carolina significantly exceeded the national average.

[10] The data on the grams of opioids distributed in South Carolina is based on an analysis of data produced by the United States Drug Enforcement Agency ("DEA") for the years 2006 to 2014 for the State of South Carolina on opioids, opiates, opium derivatives, opiate intermediates, and narcotics (herein referred to as "opioids").

[11] The summary of suspicious order reporting is based on the suspicious order reports provided by the DEA to the Attorney General's Office.



33. Defendants were responsible for much of this volume entering South Carolina, as shown below:

Distributors	Grams	% Grams	Dosage Units	% Dosage Units	Estimated Pills	% Estimated Pills
MCKESSON CORPORATION	7,487,669	29.0	941,789,747	31.9	832,918,855	20.4
CARDINAL HEALTH	5,365,937	20.8	451,484,441	15.3	1,021,223,429	25.0
AMERISOURCE BERGEN CORPORATION	1,939,736	7.5	203,355,022	6.9	344,230,822	8.4

34. Although ARCOS data is not available from 2015 to present, other sources show a growing volume of opioids distributed in South Carolina. According to public information, the overall number of opioid prescriptions in South Carolina increased in 2015. That year, there were

nearly 4.5 million opioid prescriptions filled in the State — more than 1.5 times the national average.

35. Even though the volume declined by a million pills in 2016, there were still more than 70 million opioid pills dispensed in South Carolina in 2016 than 2010--already an artificially high baseline given the surge in prescriptions and distribution at that time. According to media reports, in 2016, 26 of 46 South Carolina Counties had more prescriptions dispensed than people. In 2017, opioids were prescribed in South Carolina at a rate of 79.3 opioid prescriptions for every 100 persons, far higher than the national average of 58.7 prescriptions for every 100 person. Even with a decrease in prescriptions from the previous year, there were still **297,920,468 opioid pills** dispensed in South Carolina in 2017, an extraordinary volume compared to the state's population of approximately 5 million. According to the Governor, there were approximately 5 million opioid prescriptions issued in the state in 2018, enough for each man, woman, and child in the state to receive a prescription.

36. Out of this extraordinary volume, Defendants, as discussed below, systematically and repeatedly failed in their obligations to maintain effective controls against diversion. Their failure to report and halt suspicious orders of opioids and continued shipments of such orders into South Carolina resulted in obscene volumes of pills coming into the State for more than a decade.

2. Defendants Pursued Profits at the Expense of Public Health and Safety.

37. As described further below, for over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. Through the SCCSA and CSA, Defendants are subject to statutory obligations enacted to prevent oversupply and diversion into the illicit

market — legal duties specifically designed to protect the public health and safety.[12] These statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors would not fall. Together, these laws set standards of care that make clear that wholesalers of controlled substances possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

38. Further, these laws set standards of care that make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, with the deeply tragic and entirely foreseeable — and avoidable — consequences that South Carolina has experienced.

39. As explained below, Defendants are obligated to prevent diversion, to report suspicious orders and not to fill those orders unless due diligence disproves those suspicions. Their obligations to maintain effective controls against diversion stem from multiple sources.

40. First, Defendants are required under the SCCSA to monitor, detect, report, investigate, and refuse to fill suspicious orders. Distributors must obtain a registration from DHEC to distribute or dispense controlled substances in the State. The SCCSA requires that registration be consistent with the public interest, which in turn, requires "[m]aintenance of effective controls

[12] *See, e.g.*, S.C. Code § 44-53-300 (authorizing DHEC to register distributors only if registration is consistent with the public interest, including any factors relevant to and consistent with public health and safety); 21 U.S.C. § 801(2) (finding that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people").

against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels." S.C. Code § 44-53-300(a). In this respect, the SCCSA parallels the federal CSA. Under federal law, distributors' operations must be "consistent with the public interest," 21 U.S.C. § 824(a)(4), and "public health and safety." 21 U.S.C. § 823(b).

41. Requirements under federal law, both independently paralleled and incorporated in South Carolina law, are clear and exacting. Enacted in 1970, the CSA and its implementing regulations created a "closed system" of distribution; every entity that handles controlled substances is required to meet specific record-keeping and distribution standards. As the Congressional Record reflects, "Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." 970 U.S.C.C.A.N. 4566. In enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

42. Specifically, as federal registrants, Defendants are required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. This includes a duty to monitor, detect, report, investigate, and refuse to fill suspicious orders. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74.[13] To allow for action by law enforcement, the duty must be carried out

[13] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal*

without delay; distributors "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered* by the registrant."[14]

43. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74(b). These criteria are not exclusive; any one of them can trigger the duty to report and stop shipment, and other factors not listed in the regulations also may point to suspicious orders. A volume of orders of a controlled substance disproportionate to the population or historic use in an area, for example, may provide reason for suspicion. In addition, orders skewed toward high-dose pills or drugs valued for abuse should alert distributors to potential diversion.

44. To comply with the law, distributors must know their customers and the communities they serve. Each distributor must "perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017). This includes a "reasonable investigation to determine the nature of a potential customer's business before it sells to the customer, and the distributor cannot ignore information which raises serious doubt as to the legality of a potential or existing customer's business practices." *Id*. (alterations and internal quotation marks omitted) (quoting *Southwood Pharms.*, Inc., 72 Fed. Reg. 36,487, 36,498 (DEA July 3, 2007)).

Health, Inc. Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter, "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter, "2007 Rannazzisi Letter").

[14] *Id*. (emphasis added); *see also* https://www.deadiversion.usdoj.gov/pubs/manuals/sec/other_sec.htm#good_faith (registrant must inform the DEA of suspicious orders "immediately upon discovery").

45. A customer's order data and the data of other similar customers provide detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion.

46. Second, Defendants are prohibited under South Carolina law from engaging in unfair acts and practices in trade and commerce. *See* S.C. Code Ann. § 39-5-20(a). Defendants must not engage in conduct "which is offensive to public policy or which is immoral, unethical, or oppressive." *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 414 S.C. 33, 56-57, 777 S.E.2d 176, 188 (S.C. 2015). To that end, Defendants' conduct in flooding the market with opioids, failing to maintain effective controls against diversion, and fueling an illicit black market injures consumers, offends South Carolina public policy, and is immoral, unethical, and oppressive.

47. This is particularly true given that, at the same time, Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, claiming to take all reasonable precautions to prevent drug diversion. As described in Section IV.E, Defendants publically touted their purportedly state of the art suspicious order monitoring systems and processes and professed commitment to legal compliance as evidence of their of corporate responsibility.

48. Third, under the common law, Defendants have a duty to exercise reasonable care and to avoid creating a public nuisance. Because opioids are dangerous, addictive drugs, the standard of care Defendants must meet in distributing them is appropriately high.

49. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under South Carolina and federal laws with respect to preventing diversion. First, they must set up a system designed to detect and reject suspicious orders. Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

50. All suspicious conduct must be reported to relevant enforcement authorities.[15] Further, Defendants must not fill or ship any suspicious prescription or order unless they have conducted an adequate investigation and determined that the prescription or order is not likely to be diverted into illegal channels.[16] Reasonably prudent distributors would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

3. Defendants are Uniquely Positioned to Detect Suspicious Orders.

51. Defendants' role in the supply chain provides them with detailed data on the shipment of opioids to pharmacies and other dispensaries (such as hospitals) both over time and in real time. As described below, they are enmeshed at virtually every level of the opioid supply chain, and mine detailed information that they leverage into increased profits. Possession of this extensive information equips distributors to readily and efficiently identify potentially suspicious orders of opioids. Given Defendants' market share nationally, they have particularly extensive

[15] *See infra* ¶¶ 37-49.

[16] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

information. Indeed, based on Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

52. With access to detailed data and their analytical capabilities, Defendants are able to determine, down to the pharmacy and the type, number, and dose of each pill, the volume of opioid sales across South Carolina and the country. Defendants have the ability to see total orders by their customer pharmacies, including non-controlled substances and combinations of drugs that signal diversion — information the DEA does not have. For example, while they may not know the precise details of another distributor's market share, distributors can obtain dispensing data from their pharmacy customers that show the total volume of controlled substances the pharmacy dispenses, the physician associated with each prescription, and the method of payment used to pay for the prescription.

53. In addition to their own data from shipping prescription drugs to customers, Defendants also obtain national, regional, state, and local prescriber-level data from various companies, known as "data vendors," that collect and sell data, such as IQVIA (formerly IMS Health, Inc.), Wolters Kluwer, and Verispan. CVS Caremark's Director of Managed Care Operations, Scott Tierney, previously testified in other litigation that CVS, which is the largest pharmacy chain in South Carolina, comprising some 20% of the purchasing market, would provide the data vendors with "prescriber level data, drug level data, plane level data, [and] de-identified patient data,"[17] illustrating the level of detail available to Defendants through data vendors.

54. The breadth and depth of the data available to and collected by Cardinal, for example, was made clear in a 2001 news article describing Cardinal's joint venture with CVS and

[17] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-246 (Feb. 22, 2011).

retailers Wal-Mart, K-Mart, and Albertsons, all of which have pharmacy operations, to "collect and market real-time prescription-drug sales data."[18] The venture, called ArcLight Systems LLC, had access to data from nearly 1 billion prescriptions.

55. This information would have allowed distributors to analyze and track their competitors' sales and to determine their relative market shares (and thus the total supply of opioids in an area).[19] This extensive information likewise would have allowed Defendants to track and identify instances of overprescribing and orders that raised red flags. In fact, an expert for a data vendor testified in an unrelated proceeding that this information could be used to track and report suspicious orders of controlled substances.[20]

56. Sales representatives from Defendants are also in frequent, direct contact with their pharmacy customers. Sales and compliance personnel are tasked with investigating new potential pharmacy customers to determine whether they can be trusted to handle controlled substances. Defendants' sales personnel also are responsible for regularly visiting existing customers to maintain and expand the products and services they sell. They know, for example, which pharmacies are in less populated areas, have a high proportion of cash transactions, or do not offer non-prescription products—all reds flag of diversion.

57. The Defendants also offer their pharmacy customers a broad range of added services as stand-alone services or through their franchise programs (McKesson's Health Mart,

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[18] *Cardinal Health, Others Form Prescription-Data Analysis Firm*, BizJournals.com (July 30, 2001), available at: https://www.bizjournals.com/columbus/stories/2001/07/30/daily2.html.

[19] A Verispan representative testified that the Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[20] In *Sorrell*, expert Eugene "Mick" Kolassa testified that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health Inc.*, 2011 WL 687134, at *204 (Feb. 22, 2011).

Cardinal's The Medicine Shoppe and Medicap Pharmacy, and AmerisourceBergen's Good Neighbor Pharmacy), giving them still more insight into their customers' practices. For example, Defendants provide pharmacies sophisticated ordering systems and other database management support, as well as marketing programs and patient services.[21] McKesson's AccessHealth provides integrated back-office services with assistance with pharmacy benefit manager (PBM) audits, and its RelayHealth offers information technology solutions to "streamline communications between patients, providers, payors, pharmacies, pharmaceutical manufacturers, and financial institutions."[22] Cardinal's subsidiary, Kinray, assists independent pharmacies in managing business operations, increasing market share, and improving their reimbursements.[23] Through its Good Neighbor Pharmacy program, AmerisourceBergen offers "expert business coaches" to provide "guidance on every aspect of independent pharmacy operations," pharmacy analytics through its InSite program, and contract and third-party reimbursement negotiation through Elevate Provider Network, its pharmacy services administration organization ("PSAO").[24]

58. Defendants also have significant information on a pharmacy's total orders of opioids, beyond what each of them supply in another respect as well. Distributors can request and are expected to review, pursuant to their obligations to know their customers, a new pharmacy

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[21] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

[22] RelayHealth, *Corporate Overview*, *available through Internet Archive at* https://web.archive.org/web/20180106063929/http://www.relayhealth.com/about-us/corporate-overview.

[23] *See* Cardinal Health, Press Release, *Cardinal Health To Acquire Kinray for $1.3 Billion*, Nov. 18, 2010 (noting that the addition of Kinray will "significantly expand" Cardinal's ability to serve retail independent pharmacies and will give Kinray customers the benefit of Cardinal's "value-added services").

[24] AmerisourceBergen, *Business Growth and Expert Guidance: Pharmacy Solutions*, https://www.amerisourcebergen.com/abcnew/solutions-pharmacies/business-growth-and-expert-guidance.

customer's dispensing data, which allows them to determine the amount and proportion of opioids provided by another distributor.

59. The information available to wholesalers is not limited to pharmacy orders. Defendants also have detailed information on prescribing, which they sell to manufacturers. Cardinal's manufacturer business services include pharmacy marketing communications, regulatory consulting and healthcare analytics, which offer provider insights through Cardinal's "unique relationships with specialty practices across the country."[25] Cardinal's website states that it will "recruit physicians to participate in studies related to [a manufacturer's] drug" and "capture and analyze prescribing, dosing and other patient management patterns … from a particular practice."

60. Upon information and belief, Defendants also contract with various manufacturers to advertise their opioids to pharmacies and to conduct their copayment assistance and "adherence" programs (reminders to patients to refill their opioid prescriptions), which gives them access to information on manufacturers' marketing strategies and messages and patients' use of opioids. Distributors assisted the manufacturers in these efforts, playing an integral part in these successes.

61. Each of the Defendants offered manufacturers services that promised to enhance the launch and distribution of their opioid products.

62. As a result of these multiple services, subsidiaries, and data sources, the Defendants have a role in and have knowledge of virtually every link in the supply chain, from manufacturer to patient. They have information on ordering, prescribing, dispensing, and use of controlled and non-controlled substances. They also have insight into their market share and whether their

[25] Cardinal Health, *Provider Insights*, *available at* https://www.cardinalhealth.com/en/services/manufacturer/biopharmaceutical/real-world-evidence-and-insights/market-insights/provider-insights.html (last accessed Aug. 10, 2018).

pharmacy customers are purchasing prescription drugs from other distributors. These sources of information both enable and obligate them to do far more in detecting, reporting, and preventing diversion.

4. Defendants Understood and Acknowledged Their Obligations to Maintain Effective Controls Against Diversion, and the Consequences of Failing to Meet Them Were Foreseeable.

63. Defendants have long been aware they had an important role to play in the closed system of opioid distribution, and they knew or should have known that their failure to comply with their obligations would have serious consequences. Indeed, the DEA has repeatedly informed Defendants about their legal obligations, including obligations that were so obvious that they simply should not have required additional clarification. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime. As former DEA agent Joseph Rannazzisi recently explained during a deposition in the MDL:

> Q. Someone says "Don't steal," do you have to put in there "from a supermarket"?
>
> A. No.
>
> Q. Someone says "Don't trespass on the property," do you have to put "wearing tennis shoes"?
>
> A. No.
>
> Q. Next, you got asked: "Well, you never instructed the companies to keep their files." Do you remember that?
>
> A. Yes, sir.
>
> Q. Would old files be important in monitoring -- in your ongoing monitoring? Would it be important that a company keep their files so that they can look back at them?
>
> A: Absolutely. That's the -- the whole idea behind maintaining a due diligence file is you have a history of purchases. That way you could

> see what they're doing and where they're going with their purchases.[26]

64. As early as 1984, correspondence between the DEA and the NWDA[27] illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting "**DEA has interpreted 'orders' to mean prior to shipment.**"

65. In April 1987, the DEA sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers." According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained: "any system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program." Another area of issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

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[26] Rannazzisi Dep. at 646:20-647:19.

[27] In 2000, the NWDA was renamed the "Healthcare Distribution Management Association" ("HMDA"). The HDMA's membership included CVS. In 2016, HDMA was once again renamed and is now known as the Healthcare Distribution Alliance ("HDA").

66. In 2007 and 2008, the Healthcare Distribution Management Association ("HDMA,") now known as the Healthcare Distribution Alliance ("HDA"), a trade association of pharmaceutical distributors in which Defendants have long been members, began developing "Industry Compliance Guidelines" ("ICG") that aimed to outline certain "best practices" for the distributors. As part of its development of the ICG, the HDMA met with the DEA on at least three occasions. The HDMA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum. Internal discussions concerning the ICG further demonstrate the industry's knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDMA noted that one potential downside of this approach was that "DEA correspondence/interpretation do not support this practice."[28]

67. The HDMA released the ICG in 2008 and, in doing so, it emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[29]

68. Nevertheless, distributors including Defendants did receive repeated and detailed guidance, including, for example, concerning their obligations to know their customers and communities they serve. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should

[28] HDA_MDL_000213058.
[29] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

Ask Prior to Shipping Controlled Substances,"[30] which suggests that distributors examine, among other things, the ratio of controlled vs. non-controlled orders placed by the pharmacy; the methods of payment accepted; whether, why, and to what extent the pharmacy also orders from other distributors; and the ratio of controlled substances the distributor will be shipping relative to other suppliers.

69. The DEA also repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

70. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."[31] The CSA requires that distributors (and

[30] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[31] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,"[32] described above, from which certain data was recently made public.

71. The DEA has hosted many different conferences throughout the years to provide registrants, including Defendants, with updated information about diversion trends and their regulatory obligations. Such conferences have included, for example, an "industry conference in which [it] brought manufacturers, distributors, importers together"[33] and Distributor Conferences. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

72. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including Cardinal, McKesson, and AmerisourceBergen. The 2006 letter emphasized that distributors are:

> one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

[32] U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, https://www.deadiversion.usdoj.gov/arcos/index.html.

[33] Prevosnik Dep. (MDL) at 76:23-77:3.

73. The letter also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[34]

74. The DEA sent a second letter to distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they share and must each abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[35] DEA's letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting ARCOS data to the DEA).

75. During a 30(b)(6) deposition in the MDL, the DEA's Unit Chief of Liaison was asked whether the DEA made it "clear to industry that the failure to prevent diversion was a threat to public safety and the public interest." In response, he testified:

> Yes, I think it's established in 823 [the Controlled Substances Act] where it's part of our -- part of the registrant that is applying to be a registrant understands that they have to maintain effective controls . . . . they also know that these drugs themselves are scheduled controlled substances for a particular reason, because they're addictive, psychologically and physically they're addictive, so they know that these drugs have these properties within themselves. **So they would understand that these drugs are categorized or scheduled in that manner because they have the potential to hurt**.[36]

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[34] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter").

[35] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 ("2007 Rannazzisi Letter").

[36] Prevoznik Dep. Vol III at 942:3-8; 942:11-943:3 (emphasis added).

76. And Defendants did understand. As described above, Defendants have themselves acknowledged their understanding of the potential consequences of their failure to report and cease shipping suspicious orders.

77. More recently, a corporate representative testifying on behalf of McKesson in a MDL deposition acknowledged that violations of the CSA's requirements result in a substantial and detrimental effect on the health and general welfare of the American people.[37] During the same deposition, he further testified that McKesson accepts partial responsibility for the societal costs of the opioid epidemic now facing the nation.

5. Defendants Failed to Maintain Effective Controls Against Diversion and Oversupplied Opioids into South Carolina.

78. In its 2017 investigation of wholesale distributors, the U.S. House of Representatives Committee on Energy and Commerce ("Energy and Commerce Committee") noted that Defendants, despite "settlement agreements and the subsequent policy enhancements" and "[d]espite efforts by DEA to educate distributors about their responsibility to report suspicious orders," "failed to address suspicious order monitoring in critical ways" and in many instances "appeared to turn a blind eye to red flags of possible drug diversion." These systemic failures made no exception for South Carolina.

79. Despite their compliance obligations, Defendants shipped far more opioids into South Carolina than could have been expected to serve legitimate uses, ignored other red flags of diversion, failed to investigate their customers and to detect suspicious orders, and chose not to report or reject even those suspicious orders that were, or should have been, evident.

[37] 7/31/18 Hartle Depo. at 43:22-44:5.

80. Given the volume and pattern of opioids distributed in the State, described in detail above, Defendants were, or should have been, aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders. They did not.

81. According to data from the ARCOS database, between 2006 and 2014, Cardinal alone supplied more than 1 billion (1,021,223,416) estimated 10 mg equivalent pills in South Carolina. Meanwhile, McKesson supplied 832,918,849 estimated 10 mg equivalent pills, and AmerisourceBergen 344,215,266 estimated 10 mg equivalent pills in the State. As shown in Paragraphs 31-33 above, the data shows that the volume grew dramatically, particularly from 2006 to 2012. As described in Paragraphs 34-35, prescription volumes remained high thereafter, with more than half of South Carolina counties reporting more prescriptions than people as recently as 2016.

82. This volume of opioids and its increase after 2006 indicated that distributors were dramatically oversupplying opioids into the State and raised a red flag that not all of the prescriptions being ordered could be for legitimate medical uses. As described above, per capita opioid prescriptions in South Carolina significantly exceed the national average for the entire period for which ARCOS data is available, and the most recent information available indicates that by other measures as well, South Carolina has significantly higher prescription rates than the nation as a whole.

83. Other events, including pharmacy robberies, also should have raised red flags that diversion, abuse, and addiction in South Carolina was widespread. Pharmacy robberies have made news in South Carolina, including as recently as April 2019, when a robber entered a Walgreens

store and "demanded all the pain pills,"[38] and a CVS was robbed of narcotic painkillers, prompting a media report that "[i]t has become all too common for pharmacies to be held up and the thieves not even ask for money."[39]

84. As also described above, Defendants would have had specific and detailed information giving them insight into diversion in South Carolina. Additionally, even the more limited information shows that they would have been aware of both systemic failures and of red flags relating to pharmacies, orders, prescribers, and patients in South Carolina.

85. The information on the supply of opioids distributed in South Carolina, along with the information known only to Defendants, including their analysis of individual order data and other data sources described above, would have alerted them to potential diversion of opioids in South Carolina.

McKesson

86. McKesson's policies and procedures for the distribution of controlled substances nationally and in South Carolina were recorded in its Drug Operations Manual, known as Section 55, as early as 1997. The Manual underscores the fact that McKesson has long understood its obligation to report and halt suspicious orders. For example, it emphasizes that "[c]ontrolled substance order fillers must be aware of our responsibilities. They are expected to report to management any unusual purchase request before orders are filled." In September 2005, one month after starting the Distributor Initiative described in Paragraphs 70-71, DEA officials met

[38] Andrew Dys, *Rock Hill Pharmacy Near Winthrop University Robbed; Suspects Sought, Police Say* (Apr. 24, 2019), https://www.heraldonline.com/news/local/crime/article229619909.html

[39] Paul Kirby, Irmo Police Department Investigating Saturday Morning CVS Robbery, (Apr. 27, 2019), https://www.swlexledger.com/single-post/2019/04/27/Irmo-Police-Department-investigating-Saturday-morning-CVS-robbery

with McKesson to alert the company to its excessive sales to pharmacies filling illegal online prescriptions.

87. However, despite being well aware of its obligations, McKesson consistently failed to design and implement a system that effectively identified suspicious orders. Moreover, even when McKesson's system *did* identify suspicious orders, McKesson nevertheless continued to ship the orders and failed to report them to the DEA. McKesson's practices in South Carolina reflect these systemic failures.

1. *McKesson's Monitoring Program Was, on its Face, Ineffective Because it Improperly Relied on Thresholds.*

88. From 1997 to 2007, McKesson's suspicious order monitoring policy, including in South Carolina, consisted of retrospective reports documenting previous sales of controlled substances to customers whose sales exceeded three times the customer's annual average for that drug code. The Manual contained no requirement that orders flagged by the system be reported to the DEA or that such orders be investigated and cleared prior to shipment.

89. McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders as required by the federal CSA, whose requirements parallel South Carolina law. In particular, McKesson's Regulatory Affairs Director, David Gustin, stated in an internal email that "the previous reports were not the exclusive and proper response to this regulation," as the company has an "obligation to report 'suspicious orders" and "[s]imply reporting larger than usual orders does not [meet the spirit and letter of the regulation] when there are so many plausible and routine reasons for orders to be 'larger than normal.'"

90. In August 2006, McKesson received an Order to Show Cause from the DEA relating to compliance failures at its Lakeland, Florida facility. Earlier that year, McKesson had also received a memorandum from the DEA highlighting, among other issues, that McKesson by

its own admission was unable even to "provide a plausible explanation" for supplying over two million dosages over a 21-day period to a pharmacy customer which the DEA had already identified as a concern to McKesson. During discussions with the DEA, McKesson conceded that these extremely large orders were not flagged under its suspicious monitoring system, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes under that system. A November 1, 2007 show cause order from the DEA followed for McKesson's failure to maintain effective controls to prevent diversion against McKesson's Landover, Maryland distribution center, further illustrating the systemic nature of the violations.

91. McKesson then created an "improved" monitoring program, which it called the Lifestyle Drug Monitoring Program ("LDMP"), in 2007. However, rather than monitor orders for all controlled substances, the LDMP only monitored four specific controlled substances. For these four drugs, McKesson set an 8,000 monthly dosage unit threshold for every McKesson customer nationwide, with a review process triggered only if that threshold was met. Moreover, McKesson ignored the dosage unit thresholds set by the LDMP and nevertheless continued to ship large quantities of oxycodone and hydrocodone to its customers. For example, in 2007, McKesson sent more than 3 million doses of hydrocodone to a West Virginia pharmacy – despite the fact that this shipment was more than 36 times the threshold set by its new LDMP. Nationwide, McKesson's threshold was only a soft cap, so that orders oxycodone and hydrocodone exceeding 8,000 units were not blocked, but instead investigated after McKesson had already made the sale. This failure illustrates systemic flaws, from which operations in South Carolina would not have been exempt. Deposition testimony in the MDL by a former McKesson employee confirmed the LDMP had no mechanism to block orders once the 8,000 unit threshold was met and while an investigation was ongoing. Further, internal documentation shows that pharmacy customers were routinely

permitted to exceed the monthly dosage thresholds before McKesson completed a due diligence review.

92. Throughout this time, McKesson's program, and Manual implementing the program, included no requirement to block orders that were deemed excessive for purposes of DEA reporting. McKesson undertook no investigation of the legitimacy of such orders, other than confirming whether certain orders were input through erroneous entries.

93. In 2008, McKesson entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with the DEA, attached as Exhibit A, to settle allegations made by six U.S. Attorneys that the company failed to report suspicious orders of hydrocodone (and another controlled substance, alprazolam). The federal government found that three of McKesson's distribution centers filled hundreds of suspicious orders by pharmacies that were involved in the illegal online prescription scheme about which the DEA warned McKesson in their 2005 meeting. In addition to paying $13.25 million in fines, McKesson temporarily suspended the distribution of the two drugs from two of its distribution centers. In addressing McKesson's wrongdoing, DEA Administrator Leonhart stated that "[b]y failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country."[40] The national scope of McKesson's SOMS program and the systemic nature of the CSA violations reflect on McKesson's conduct nationwide, including in South Carolina.

94. The agreement provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious

[40] Shannon Henson, Law360, *McKesson Ponies Up $13M To Settle Drug Claims* (May 5, 2008), https://www.law360.com/articles/55133/mckesson-ponies-up-13m-to-settle-drug-claims.

orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program." As a part of this settlement, McKesson once again launched a new, national monitoring program that would have been applied to shipments to South Carolina – the Controlled Substances Monitoring Program ("CSMP"). It was not until development of the CSMP that McKesson began making any effort to block suspicious orders. However, like its LDMP, this monitoring program was also woefully inadequate.

95. In South Carolina, the Attorney General identified instances in which, during this time frame, McKesson appeared to be acting as a secondary supplier to pharmacies dispensing large volumes of opioids in the state, including examples in Greenville and Holly Hill.

96. In its April 24, 2018 letter to the Energy and Commerce Committee, McKesson asserted that one of the key elements of its revised CSMP is its controlled substances threshold management program, which McKesson describes as "a cutting-edge controlled substances threshold management program." The letter continued: "McKesson's model analyzes each customer order against established monthly thresholds to determine whether that order should be filled. If a customer's order exceeds the monthly threshold, that order is required to be blocked and not filled. McKesson reports each blocked order to DEA pursuant to 21 C.F.R. § 1301.74 and to state monitoring agencies pursuant to applicable state reporting regulations . . . "

97. There are at least three deficiencies in this approach. First, a threshold-based compliance system is both under- and over-inclusive. Even an order that is within a customer's threshold may be suspicious because, for example, it includes a disproportionate share of high-dose opioids. Conversely, an order that exceeds threshold may not be suspicious. Orders, for example, frequently exceed threshold at the end of the month, and are filled at the start of the next month, when the threshold re-sets. Yet, McKesson still reports those orders, burying orders that

it believes may actually be suspicious among those McKesson believes are no more than typical inventory management issues.

98. Second, McKesson's thresholds are based on the already too high baseline for opioid distribution. Because thresholds are set based on pharmacies' historic patterns, a pharmacy that received a volume of opioids that is too high for the expected use in its area, for example, would continue to receive orders at that too-high threshold. Notably, McKesson set thresholds based on purchases from the 2007-2008 time period, a year that the Department of Justice has noted was a one "in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies." Moreover, McKesson took that inflated baseline and added, without any compliance justification, a 10% bump, which excludes potentially suspicious orders within that "extra" threshold. Internal documents show that thresholds were initially set under the CSMP by reviewing the customer's 12 month purchase history for each drug base code, reviewing the highest month of purchases in that 12 month period, and adding a 10% buffer to that purchase amount. Thresholds could then be adjusted thereafter through a process referred to as a threshold change request ("TCR").

99. Internally, Gustin (Director of Regulatory Affairs), stated in August 2011 that: "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."' Despite these concerns, no serious efforts were undertaken to systematically reduce thresholds until 2015, a full four years later.

100. Third, McKesson does not apply any metric that assesses an area's population to determine whether orders are suspicious. A small pharmacy serving a town of 10,000 people could order 25,000 opioid tablets month after month without being flagged or reported. Nor does McKesson add up the volume of orders for a particular city or across the state to determine whether the overall supply is reasonable or suspicious. A volume of orders of a controlled substance disproportionate to the population or historic use in an area, however, may provide reason for suspicion.

101. These flaws are particularly problematic because McKesson's compliance system depends upon thresholds. The only other circumstance in which a customer will be investigated is if McKesson receives an enforcement tip or if it is assessing a new customer.

102. Thus, McKesson was "neither rehabilitated nor deterred" by the 2008 settlement, as a DEA official working on the case that lead to the subsequent 2017 settlement noted.[41] Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case," "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.[42] Instead, the DEA officials said, the company raised its own thresholds on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[43]

2. *Orders that exceeded thresholds merely prompted threshold increases.*

[41] Lenny Bernstein and Scott Higham, "*We Feel Like Our System Was Hijacked": DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post, December 17, 2017, *available at* https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html

[42] *Id.*

[43] *Id.*

103. Another systemic flaw, from which McKesson's South Carolina practices would not be exempt, was that McKesson's threshold change request process creates additional incentives to inflate thresholds. In theory, customers that have a legitimate reason to purchase additional controlled substances (e.g., the closure of an alternate pharmacy or the opening or a new nearby doctor's office) can seek to increase their threshold level. In practice, an order that McKesson flagged for exceeding the pharmacy's threshold merely signaled that the pharmacy's threshold needed to be increased.

104. Not only did McKesson raise thresholds after an order is flagged as suspicious, it often raised them before an order was likely to go over a customer's allotted threshold. Sales representatives were given a "threshold warning report" of customers that were nearing threshold for them to call, which was used for years, to great effect, as a preemptive tool to increase thresholds before orders had to be blocked or reported. In discussing these reports in an October 2006 internal email, an employee noted that this practice allowed work to begin on justifying an increase before any "lost sales" occurred from imposing a limit, and emphasizing that McKesson was "in the business to sell product."[44]

105. Internal documents reflect that, as of 2011, McKesson knew that it needed to "tighten up" both its due diligence on accounts that had undergone significant changes in controlled substances purchasing, as well as its "process regarding granting [threshold] increases."

[44] MCKMDL00543971. McKesson would later effectively acknowledge the impropriety of this practice in a November 2013 announcement to its employees of new policy pertaining to threshold warning reports. This presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time." MCKMDL00476786 at 00476791. And announcing a policy, of course, does not mean that McKesson abided by it or reformed its systemic failures.

McKesson knew it had "gotten to a point where certain % of increase [we]re almost automatic" and it "too easily accept[ed]" what its own correspondence described as "'reasons' like 'business increase' for raising thresholds by small amounts." These increases, cumulatively and incrementally, could make a big difference, yet McKesson effectively admitted it was not requiring submission of supporting data to justify the increase.

106. Gustin, was concerned enough with the state of affairs to comment to his colleagues that "[w]e as DRAs [Directors of Regulatory Affairs] need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time." Another Regulatory Affairs Director, Michael Oriente, responded: "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up."

107. In August 2014, the Department of Justice noted that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons.

108. McKesson's new policy further illustrates how the company often bypasses its reporting responsibilities by adjusting thresholds, so that fewer orders are flagged as suspicious. McKesson established its thresholds using a national average, failing to factor in an area's population or provide any comparison to similar pharmacies in the region. As explained above, however, opioid distribution rates in South Carolina were well above national averages. Moreover, distribution of opioids was not uniform throughout the State. Instead, particularly high volumes of these addictive drugs made their way to certain geographic areas, another red flag of potential diversion in these areas and in the State more generally.

3. *McKesson Systemically Failed to Identify and Report Suspicious Orders*

109. Despite its professed commitments to reform in 2008, McKesson continued to be deficient in its compliance, both nationally and in South Carolina.

110. For example, based on records produced by the DEA, one of McKesson's largest distribution centers did not report *any* suspicious orders until March 2012. Nationally, from 2008 to 2012, McKesson reported almost no suspicious orders of opioids, and reported no suspicious orders of opioids in South Carolina.

111. In connection with the investigation of McKesson that led to the 2017 settlement, the DEA and DOJ concluded that McKesson's desire for increased sales and customer retention had overridden its obligations to report suspicious orders and jeopardized the health and safety of people around the country. The DEA and DOJ also described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic."

112. Ultimately, on January 5, 2017, despite having notice and nearly nine years to improve its compliance since its 2008 settlement, McKesson entered into another Administrative Memorandum Agreement ("AMA") with DEA and agreed to pay a $150 million civil penalty—the largest penalty leveled in DEA's history against a distributor. A copy is attached as Exhibit B. A DEA memo outlining the investigative findings, stated that McKesson "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[45]

[45] Lenny Bernstein & Scott Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper,* The Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.bb606509a764

113. In the AMA, McKesson admitted that, from January 1, 2009 through January 17, 2017, at 12 of its distribution facilities, it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the [2006 and 2007] DEA Letters."[46] McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion . . . in violation of the CSA and the CSA's implementing regulations . . . ."

114. As part of the AMA, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities, some of which investigators found "were supplying pharmacies that sold to criminal drug rings."[47] The Department of Justice recognized as part of its investigation in 2013 and 2014 that there was a "nationwide" and "systemic" failure on McKesson's part to report suspicious orders and otherwise maintain effective controls against diversion. McKesson's compliance failures were an issue across all of its distribution centers, including those that distributed to South Carolina.

4. *McKesson Lacked Adequate Due Diligence Policies and Prioritized Sales Over Safety.*

115. McKesson's due diligence policies for both its new and existing customers were also inadequate to satisfy its legal obligations and to guard against diversion in South Carolina.

116. Under McKesson's CSMP, the process for evaluating new customers to determine whether to supply them with controlled substances consisted of questionnaires, which were filled out by the pharmacy or by sales representatives (who have financial incentives based on new customers and, as explained below, opioid sales). The information supplied in these questionnaires (which were only required in some instances) was rarely verified by compliance staff, who depend

[46] AMA at 5.
[47] Bernstein & Higham, *supra* note 45.

upon pharmacies to self-disclose, for example, their cash payment rates or employees with criminal records. McKesson's investigation of new customers consisted only of internet searches on the pharmacy, a check of its licensing status, review of its unverified questionnaire, photos of its building, and reviews of its ordering history; seldom did McKesson conduct a site visit or even call the pharmacy. This surface-level review falls short of the DEA's suggested "know your customer" guidance. It also stands in sharp contrast to McKesson's willingness, as described above, to make frequent sales calls on and contact with existing customers, both for its own benefit and to assist opioid manufacturers in their marketing efforts.

117. McKesson also lacked adequate policies for conducting due diligence investigations of its chain store pharmacy customers.

118. For example, in a January 9, 2009 policy entitled "CVS CSMP: Threshold Review," McKesson directed its employees to approve automatic threshold increases for CVS "without further CVS explanation," and to only seek justification for increases deemed "extraordinary" in order to "minimize disruption of business." In other words, McKesson's procedures were driven not by its obligation to report "unusual" (not "extraordinary") orders, but by its business interests.

119. Further, in the MDL, McKesson's Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for its national chain pharmacy customers; instead, it generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.

120. McKesson's legal obligations to prevent diversion extend equally to chain pharmacies and small, independent pharmacies. However, McKesson's CSMP, its sole program

for tracking and reporting suspicious orders, applied only to independent and small to medium chain retail pharmacies ("ISMC customers") until April 2018.

121. Upon information and belief, McKesson continues to work with chain pharmacies at the corporate level, rather than on a pharmacy-by-pharmacy basis. However, as the DEA has made clear, "due diligence must be performed on all customers, chain pharmacies included."[48]

122. Moreover, despite McKesson's promises to change in earlier years and an earlier settlement, the investigation leading up to McKesson's 2017 settlement with DEA revealed "a disturbing pattern," in which a Colorado distribution center's "desire for increased sales and retaining its customers overrode its obligations to report suspicious orders," a "trend" the DEA identified "across several different areas."

5. *McKesson Failed to Maintain Effective Controls Against Diversion in South Carolina.*

123. McKesson was the second largest distributor in South Carolina, measured by 10 mg equivalent pills, from 2006 to 2014, the last year for which data is available. Over that time, it shipped the equivalent of **832,918,849** 10 mg equivalent pills into the state from 2007 to 2014.

124. Measured by dosage unit, McKesson was the largest distributor in South Carolina, responsible for more than 30% of distribution, and more than twice that of Cardinal, the next largest distributor by that measure.

125. McKesson failed to report suspicious orders despite the existence of orders and customers that clearly should have triggered review.

126. In fact, based on records produced by the DEA, from 2006 to 2014, it reported ***no*** suspicious orders in the South Carolina. When McKesson did begin to report in 2013, its increase

[48] Prevoznik Dep. at 1051:1-14 ("Q: In that last sentence that 'chain store due diligence reviews must not be treated any differently than independent retail pharmacy customers,' does that represent the views of the DEA? A: Yes.").

in suspicious order reports from zero to a dramatically higher number than other distributors indicates its failure to report orders sufficiently in the past. This is particularly true given that, as described above, overall sales of opioids did not experience any particularly marked spike in 2013 as compared to 2012, a year in which McKesson apparently found not a single transaction worthy of suspicion.

127. Examples of red flags of potential diversion and suspicious orders related to McKesson are included in Appendix A.

128. These examples illustrate the systemic failure to maintain effective controls against diversion that the Attorney General found occurring in South Carolina.

Cardinal

1. *Cardinal Knowingly Failed to Design a Suspicious Order Monitoring System that would have Allowed it to Properly Identify Suspicious Orders.*

129. Cardinal knowingly failed to design and operate an effective suspicious order monitoring system to identify suspicious orders in South Carolina. Prior to 2008, Cardinal tasked its distribution center's cage vault personnel[49] with its suspicious order monitoring and had no electronic system for analyzing orders.

130. As one Cardinal employee explained the system implemented in 2007:

> The manual process we perform now with the discovery of suspected excessive purchases being left up to the keyer notifying myself, or a picker/double checker/QCer questioning an amount being processed seems to leave ample opportunity for failure. A system generated flag would be a more complete or thorough method of determining spikes or excessive quantities than what we are currently performing. . . . But without "someone" bringing a suspected "excessive quantity" order to our attention, many, many more could be going out the door under our noses.

[49] The DEA requires that controlled substances be stored in secure areas (cages or vaults) that only certain distribution center personnel may access.

131. Further, employees could easily override the system's limits, even though, as Cardinal's then Quality Assurance & Compliance Manager noted in a November 2006 e-mail, "[t]his is not supposed to happen without authorization."

132. In an earlier 2005 e-mail, a Cardinal employee reported being asked about the existence, or lack thereof, of a specific protocol to monitor possible drug diversion by internet pharmacies or wholesale accounts. He explained that none of the three wholesalers asked, including Cardinal, volunteered an answer, and to his knowledge, Cardinal had no such program. Rather its practice was that "[if] a distributor or internet pharmacy customer is properly licensed and a legal entity to purchase from us, we typically do not monitor what they purchase, or track who they sell to." Further, as described further below, until 2008, Cardinal primarily reported suspicious orders to the DEA after they had already been shipped, in the form of monthly summaries called Ingredient Limit Reports (ILRs), which were manually submitted each month and accounted only for the volume of a drug purchased and were not able to track unusual patterns or frequency.

133. The DEA repeatedly took action against Cardinal in 2007 and 2008 for failing to report suspicious orders and prevent diversion, demonstrating both Cardinal's awareness of its obligations and its failure to meet them.

134. These actions include:

- On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone, attached as part of Exhibit C;

- On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone, attached as part of Exhibit C;

- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone, attached as part of Exhibit C;

- On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone, attached as part of Exhibit C;

- On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA ("2008 MOA") related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The Agreement also referenced allegations by DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado. As part of the Agreement, Cardinal agreed "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Cardinal also agreed to pay $34 million in civil penalties, attached as Exhibit C.

The 2008 MOA not only covered the Lakeland, Florida facility, it resolved allegations of Cardinal's "alleged failure . . . to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, *at all distribution facilities* ... operated, owned, or controlled by it." *See* Exhibit C.

135. Only after the DEA actions in 2007/2008 did Cardinal take steps to implement an electronic suspicious order monitoring system. From late 2007 to 2008, Cardinal hired Deloitte to develop an algorithm to establish thresholds for its customers base on the customer's size (small, medium, or large, as determined by sales) and using the average annual sales of customers, grouped by trade (e.g., retail independents, chains, hospitals, and long-term care), multiplied by three. Notably, in setting these thresholds, Cardinal ignored that the baseline calculation used to set the threshold was significantly inflated, as the United States was already in the midst of an opioid

epidemic.[50] The system was not implemented immediately, as reflected in a January 2008 internal email which explained, among other things, that "Cardinal does not yet have a system for detecting all suspicious orders.

136. Additionally, according to a former employee (2011-2014) of Cardinal's subsidiary ParMed, it was well-known that sales representatives called customers from their cell phones to avoid recorded lines in order to coach the customers on how to order in a way that would allow them to circumvent the thresholds.

137. Although Cardinal's Standard Operating Procedures set thresholds based on the type or size of a pharmacy, they wholly failed to account for other important facts, such as the population of an area that a particular pharmacy was serving, which would provide information about the expected legitimate prescription needs.

138. Another deficiency in Cardinal's system was the monitoring of thresholds by the company's sales force. From 2008 to 2010, sales representatives were expected to monitor thresholds through "Highlight Reports," monthly reports that identified "Red Flag" or "Yellow Flag" customers, based on a percentage increase in a pharmacy's controlled substance orders. Salespeople were required to visit their Red Flag customers within ten working days to look for signs of diversion and contact their Yellow Flag customers as soon as possible (presumably, more than 10 days) to understand the reason for the increased ordering. Orders that triggered a customer's classification as Red or Yellow were not stopped—a facial violation of law. After 2010, the Highlight Reports were replaced by a program called "Winwatcher," which allowed Cardinal salespeople to see what percentage of a customer's monthly threshold amount had been ordered at any given time and directed salespeople to investigate when a threshold was exceeded.

[50] Hartman Dep. 19:1-20:12; 322:4-8 9 (admitting awareness of epidemic in 2007)

139. During a May 2018 hearing before the House of Representatives' Energy and Commerce Subcommittee on Oversight and Investigations, Cardinal's Chairman George Barrett denied that "volume in relation to size of population" should be a "determining factor" in identifying potentially suspicious orders. Barrett was also asked during the hearing about an instance when a Cardinal employee flagged an especially prolific pharmacy as a potential pill mill in 2008. In that case, the Committee found no evidence that Cardinal took any action in response. Cardinal increased another pharmacy's threshold twelve times, but, once again, Barrett could not explain what factors it applied or how it made decisions to increase thresholds.

140. While Cardinal has cited blind spots due to its lack of complete data on opioids supplied to pharmacies by other distributors, Cardinal also acknowledged that a distributor can ask a pharmacy for a report with information about all of the drugs it dispensed, not just those supplied by Cardinal. Specifically, in his May 2018 testimony, Cardinal Health's Chairman of the Board confirmed, for example, that a distributor could request a dispensing report from a pharmacy that would contain information about all of the prescriptions a pharmacy sends out—not just those provided by that particular distributor. The Committee's Report also observed that Distributors can obtain dispensing data from pharmacies that shows the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription.[51]

141. During the 2018 hearing, Barrett testified that Cardinal had made significant improvements to its monitoring, explaining that Cardinal's current monitoring systems are now entirely "data driven." He testified: "I think the subjectivity of judgment of whether a pharmacy

[51] Energy and Commerce Committee, Majority Staff, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Dec. 19, 2018 ("Energy and Commerce Report), p. 112

is legitimate or not legitimate today is really not the question. We look at data, and if the data tells us there is an aberrant pattern, we simply stop." Yet, an "entirely data driven system" ignores many of the red flags identified by DEA—long patient lines, a heavily cash business, out-of-state patients—that are both known to Cardinal and essential to detect diversion of prescription opioids. Barrett also testified that, beginning in 2012, Cardinal implemented stronger compliance systems that addressed many of the company's prior compliance failures. However, in March 2017, the California Board of Pharmacy filed a complaint against Cardinal's Valencia, California facility for shipping suspicious orders from 2012 to 2015. According to the complaint, Cardinal shipped orders for controlled substances "despite patterns of irregular ordering including significant increases in orders for commonly diverted controlled substances between 2012 and 2013 and 2013 and 2014."

142. In addition to continuing to ship sharp increases of controlled substances, Cardinal also shipped increasingly larger volumes of the highest available strength of certain drugs even though orders for higher dosage strengths of opioids are a red flag for diversion. However, as Barrett acknowledged during his testimony, if the threshold was not hit, Cardinal's system would not detect red flags such as this.

143. The flaws in Cardinal's suspicious order monitoring procedures are further underscored by its communications with third-party consultants. In 2007, Cardinal hired Cegedim Dendrite (Dendrite) to conduct an audit of its Suspicious Order Monitoring system. With respect to Cardinal's ILRs, Dendrite found that because the reports were based on historical information, they are "not sufficient to monitor deviations in ordering patterns on a real time basis" and that the ILRs "do not substitute for real time automated analysis of pattern and frequency." However, Cardinal, by its own admission, did not have a policy to stop shipment of suspicious orders until

2008. As described more fully below, for more than a year, Cardinal knowingly violated the CSA's "shipping requirement" by reporting suspicious orders via ILRs, shipping the suspicious orders prior to reporting them, and conducting no due diligence to dispel suspicions of diversion.

144. As of 2012, Cardinal also still had not implemented many of the changes that Deloitte had suggested in 2007. In internal emails, Deloitte employees described the situation as "chaotic." The Deloitte emails describe Cardinal repeatedly pushing back deadlines on implementing critical changes and describe its sense of urgency as "at least . . . invisible," "if not gone completely."

145. Thus, Cardinal's compliance system was flawed in that it: (a) was limited to an evaluation of thresholds which, for the reasons described above, does not identify actually suspicious orders; and (b) failed to take into account other important measures of potential diversion, such as an area's population or a pharmacy's customers. Yet this was the system Cardinal employed in South Carolina.

2. *Cardinal Failed to Report Suspicious Orders and Continued to Ship Orders it Identified or Should Have Identified as Suspicious.*

146. Cardinal's systemic failure to promptly report suspicious orders, including in South Carolina, occurred even though it has long been aware of and has acknowledged its obligation to notify the DEA immediately upon discovery of a suspicious order.

147. Having failed to reform, on December 23, 2016, Cardinal Health once again agreed to a settlement with the U.S. Department of Justice—this time for $44 million—to resolve allegations that it violated the CSA by failing to report suspicious orders of controlled substances, including oxycodone, and admitted to systemic failures. A copy is attached as Exhibit D.

148. Additionally, Cardinal's Senior Vice President of Supply Chain Integrity testified that in 2018, Cardinal met with the DEA to discuss its failure to report approximately 14,000

suspicious orders from "across the country" from 2012 and 2015, the majority of which involved opioids.

149. This testimony reflects a corporate culture that had not changed, despite repeated admonitions. As a January 2008 internal email from Cardinal's then-CEO, Kerry Clark, observed, in the 18 months leading up to the CEO's email, Cardinal Health had accumulated nearly $1 billion in "fines, settlements, and lost business" as a result of multiple regulatory actions, including the suspension of Cardinal distribution centers' licenses for failure to maintain effective controls against the diversion of opioids. Mr. Clark noted that the company's "results-oriented culture" was perhaps "leading to ill-advised or short-sighted decisions."

3. *Cardinal Failed to Conduct Meaningful Due Diligence and Gave Complete Deference to Chain Pharmacies.*

150. Cardinal also failed to maintain effective controls, across the nation and in South Carolina, by failing to conduct meaningful due diligence to ensure that opioids ordered by its customers were not diverted into other than legitimate channels.

151. Even if a salesperson investigated and identified signs of diversion, whether or not Cardinal continued to ship to a pharmacy was a purely subjective decision. During the May 2018 Congressional hearing, Barrett was questioned about an instance where Cardinal continued to ship to a pharmacy despite the concerns of a Cardinal employee that the pharmacy filled the prescriptions of a prescriber whose office "was essentially a pill mill." In response, Barrett admitted the failures of Cardinal's previous system, noting: "I think we had a system that allowed for too much subjectivity about the legitimacy of a pharmacy."[52]

[52] House of Representatives, Subcommittee of Oversight and Investigations, Committee on Energy and Commerce; *Combating the opioid epidemic: examining concerns about distribution and diversion* (May 8, 2018).

152. In its pursuit of profits, Cardinal also gave inappropriate, unwarranted deference to chain pharmacies — even to the point of contractually agreeing to tie its own hands when it came to the largest chain pharmacy in South Carolina, CVS, by agreeing to let CVS set its own threshold quantities and adjustment percentages, as described further below.

153. In a 2006 letter to the New York Attorney General, in the context of negotiating a settlement agreement, Cardinal acknowledged that it did not perform due diligence investigations as to certain chain pharmacy customers, indicating: "certain chain pharmacies refuse to allow any sort of intrusive inspection by Cardinal or to make certifications. And these large legitimate customers can of course take their billions upon billions of dollars in business to any wholesaler in the country."[53] In other words, Cardinal did not want to agree to monitor chain pharmacies as it might lose their very substantial business if it did.

154. Accordingly, Cardinal set artificially high thresholds for its chain pharmacy customers to avoid conducting deeper due diligence into these customers.

155. Further, a 2010 internal email between two Cardinal employees shows that Cardinal still shipped suspicious orders to CVS without performing any due diligence. One Cardinal employee wrote to the other employee, "I spoke with Brian Whalen at CVS a couple of times this morning… They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this." This type of refusal to provide information should have been a red flag. Yet, Cardinal released the orders anyway. CVS was quick to remind Cardinal that its contract with CVS required it to do so. And, Cardinal's agreement with CVS in fact did grant CVS the discretion to set its threshold quantities for controlled substances at any level CVS deems appropriate:

[53] 89(5) FOIL Appeal G000804 000006 (September 27, 2006 letter to NY AG)

> CVS requires the ability to adjust (up or down) the quantity of product our stores receive, this adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. **Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.**

156. Based on this agreement, CVS did "not expect Cardinal to interrupt service to CVS stores." As described above, however, Cardinal had, and knew it had, a non-delegable to duty to perform due diligence and halt suspicious orders, even if one its large accounts would be displeased with the "interrupt[ion]." This is consistent with testimony from another former Cardinal employee that Cardinal failed to make any effort to evaluate chain pharmacies' anti-diversion programs, and instead relied on those pharmacies to police themselves.

157. As described above and further below, ignoring violations by its chain pharmacy customers and failing to conduct meaningful due diligence investigations of these customers was Cardinal's policy at least up until another settlement with the DEA in 2012. As a result, Cardinal turned a blind eye to what were often obvious violations. For example, Cardinal Health's Lakeland distribution center approved a nine fold increase in supply of oxycodone to one CVS store over a single one-year period in 2009. The following year, Cardinal once again increased the supply, this time by 63%. According to the DEA, had Cardinal conducted meaningful on-site investigations of its customers, it would have found that "approximately every third car" through the CVS drive-through lane sought to fill a prescription for opioids and that customers often requested certain brands of oxycodone "using street slang."[54] As described below and in Appendix A, Cardinal should have identified numerous red flags at both chain and independent pharmacies in South Carolina, but instead continued to ship large volumes of opioids to these stores.

[54] Leonhart Decl. in *Cardinal v. Holder*

158. In response to the DEA's Order to Show Cause and Immediate Suspension Order of Cardinal's Lakeland facility, Cardinal filed a complaint and motion for a temporary restraining order in the United States District Court for the District of Columbia. Although the Court initially granted Cardinal's motion for a temporary restraining order, it ultimately upheld the DEA's Immediate Suspension Order ("ISO") in an order which illustrates the lack of diversion controls and serious legal violations at the facility. Specifically, in denying Cardinal's motion for a preliminary injunction of the ISO, the Court reasoned:

> the factors considered by [the DEA]—including (1) the rampant pharmaceutical drug problem in Florida, (2) Cardinal Lakeland's history of inadequate anti-diversion controls, (3) the large and increasing amounts of oxycodone distributed by Cardinal Lakeland to the four pharmacies from 2009 to 2011, (4) the sizeable amounts of oxycodone distributed to 25 other pharmacies in 2011 that exceeded state and national averages, and (5) the evidence of Cardinal Lakeland's failure to monitor its chain pharmacy customers, despite clear warning signs of inadequate anti-diversion controls at those pharmacies—provided a reasonable basis for [the DEA's] conclusion that Cardinal Lakeland's continued registration posed an "imminent danger to the public health or safety" under § 824(d).[55]

159. In May 2012, Cardinal entered into a Memorandum of Agreement with the DEA wherein it admitted that "its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." A copy is attached as Exhibit E. Further, in the MDL, the DEA testified, through Thomas Prevoznik, that it was "in fact frustrated that registrants were blatantly violating the MOUs[/MOAs] from prior administrative actions" including "Cardinal Health's 2008 MO[A] and settlement which resulted in a second DEA fine."[56]

160. Cardinal's ability to adequately conduct due diligence investigations was further limited by the fact that its compliance department was woefully understaffed. In a January 2005

[55] *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 225 (D.D.C. 2012).
[56] Prevoznik Dep., Vol. II, 621:5 to 621:20

Cardinal presentation regarding Cardinal's Quality and Regulatory Affairs (QRA) department, it was noted that "[q]uality is not a mindset at Cardinal health – we are not proactive" and "[t]his is not high enough priority today[.]" It goes on to describe its QRA department as "under resourced today," and states that they "don't have enough bench strength" and there were "not enough people."

161. Still, Cardinal ignored the problems highlighted in the 2005 presentation. In a year-end review of Cardinal's compliance budget for the 2006-2007 fiscal year, it was noted that QRA staff workloads were at "full capacity," that "[e]ffective management of current projects and initiatives is difficult," and that the company lacked resources "to improve and enhance existing programs." Subsequently, in a January 7, 2008 email to members of Cardinal's Anti-Diversion Steering Committee, Vice President of Retail Marketing, Steve Lawrence, voiced his concern that QRA did not have sufficient resources. Then, on January 26, 2008, Lawrence provided an update regarding Cardinal's efforts to staff its QRA department and stressed that the staff was working "day, night, and weekends" but that the group remained understaffed. Cardinal's Vice President of QRA, Steve Reardon, admitted that although Cardinal was a company with 30,000 employees, it tasked **only three people** with responsibility for conducting due diligence reviews for more than "**20-some-odd distribution centers**," acknowledging that it was impossible for Cardinal to conduct proper investigations with such poor staffing.[57]

162. Reardon also acknowledged that Cardinal's due diligence investigations were ineffective because they required a retrospective review, testifying:

> Q. [You were shown] earlier the amount, that the tens, if not hundreds of thousands, of pills that were being ordered by some of

[57] Steve Reardon Depo. 469:20 to 470:16 (agreeing that "there's no way to do a proper investigation of all these with three people").

these pharmacies every month. But by the time we're reviewing the report, those pills are already gone and out on the street, aren't they?

A. Correct.

Q. It's not an effective system to prevent diversion if we've already sent out the pills, and then we're reviewing the report, is it?

A. It could be suspect; we could prevent it.[58]

4. *Cardinal Failed to Maintain Effective Controls Against Diversion in South Carolina.*

163. Between 2006 and 2014, Cardinal had the highest number of controlled substance transactions in South Carolina. It shipped nearly a quarter (24.4%) of all opioid pills in state – the equivalent of **1,021,223,416 estimated 10 mg equivalent pills**. Yet based on records produced by the DEA, Cardinal failed to report a single suspicious order in South Carolina until 2009. Even then, over a five year period, it reported less than half the number of suspicious orders as McKesson (despite McKesson's own reporting deficiencies), and even though McKesson had substantially fewer overall transactions than Cardinal over the same time period. Information available to Cardinal should have raised red flags.

164. Examples of potential red flags of diversion and suspicious orders related to Cardinal are included in Appendix A.

165. These examples illustrate Cardinal's systemic failures to maintain effective controls against diversion of dangerous drugs in South Carolina.

AmerisourceBergen

1. *AmerisourceBergen's "Order Monitoring Program" failed to properly identify suspicious orders.*

[58] *Id.* at 452:16-453:6 (emphasis added).

166. According to a 2017 investigation by the Energy and Commerce Committee, AmerisourceBergen "began using a daily order monitoring program in the 1980s." The program it used, or failed to use, was the same in South Carolina as nationally, and fell far short of fulfilling the obligations of a distributor of addictive narcotics in South Carolina.

167. As explained below, AmerisourceBergen lacked a meaningful system to see that it would, even as its program evolved over time.

168. A corporate representative recently testified in the MDL on behalf of the company that, from 1990-1998, AmerisourceBergen's suspicious order monitoring system identified "orders of interest" based on thresholds, which were set as follows:

> You take all the pharmacies within the category and divide by the number of pharmacies to come up with an average volume for the month per drug category. And there was a multiplier of three. Any order that was over the threshold amount would be produced [sic] an excessive order report.[59]

169. The rudimentary multiplier did not, of course, identify orders of unusual frequency. Nor did it identify deviations from normal ordering patterns. As discussed in Section IV.A.4 above, however, AmerisourceBergen would have been well aware of its obligation to consider these factors and implement a genuine *suspicious* order monitoring policy. In addition, the NWDA's Controlled Substances Manual, created by the predecessor organization to the HDA, emphasized that "an after-the-fact monitoring program as previously described (whether computer or manual) does not relieve the distributor of responsibility for policing individual orders that appear excessive. In these situations, DEA should be notified before the order is shipped . . ." AmerisourceBergen thus understand and recognized a distributor's responsibility to immediately

[59] Zimmerman Depo, 121:12-21

report suspicious orders and to refrain from shipping such orders. That was not, however, what occurred.

170. From 1998 to 2005, AmerisourceBergen ostensibly improved its system through a new threshold calculation based on a multiplier of a pharmacy's own average purchases over a rolling four-month average. The updated calculation left the deficiencies described above in place. It also failed to even consider like pharmacies' purchasing activity and paved the way for faster threshold increases by using a shorter time period to calculate the threshold. AmerisourceBergen then relied on "order fillers" at its distribution centers" to identify and report suspicious orders through a manual process after the orders had already shipped. Although AmerisourceBergen's corporate representative testified that the order fillers were instructed to report orders of unusual size or frequency, in reality there were no hardline rules for, or consistency to, this process. Rather, the order fillers were left to their discretion to subjectively determine what was suspicious.

171. The same rules for suspicious order identification and reporting applied across the country, including in South Carolina. Among the most notable flaws in this process were that it only monitored the average of each customer against its own prior orders, and there were no policies or procedures to compare customers' purchase of controlled substances with the average purchases of similar customers. Moreover, there was no system to compare Schedule II or III substances to others and no system to evaluate the frequency of orders placed.

172. In April 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order, attached as Exhibit F, against the AmerisourceBergen Orlando, one of its Florida distribution centers, alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its distribution center's DEA registration.

173. Also in June 2007, AmerisourceBergen implemented an "enhanced" controlled substance Order Monitoring Program ("OMP"). Under this program, AmerisourceBergen's Corporate Security & Regulatory Affairs ("CSRA") department established account threshold levels based solely upon account classification such as "Pharmacy, Chain, Hospital, and Distributor."

174. AmerisourceBergen subsequently reevaluated its thresholds by also considering the size of the account and by monitoring both the sales volume and the percentage of controlled substances purchased by its customers. Customers with low ratios of controlled substances, for example, could receive threshold increases with minimal due diligence.

175. By focusing largely on a customer's established threshold rather than other additional factors, AmerisourceBergen disregarded possible suspicious orders that did not exceed a particular client's threshold. Moreover, the OMP guidelines did not require reviewing a customer's thresholds to ensure that such thresholds were appropriate.

176. In 2012, AmerisourceBergen introduced additional changes to its OMP.

177. This change was intended to make the management process "more systemic and less arbitrary."

178. The 2012 policies, however, remained deficient and still permitted CSRA to override a threshold once it was exceeded. This ultimately defeated AmerisourceBergen's stated goal of making its policies "more systemic" because it continued to allow its employees to make subjective judgment calls about exceeding thresholds.

2. *Even When It Identified Suspicious Orders, AmerisourceBergen Failed to Perform Due Diligence and Still Shipped Them.*

179. AmerisourceBergen also failed to perform due diligence and halt the suspicious orders it did identify, including in South Carolina. Not only did AmerisourceBergen fail to stop

the shipment of orders it identified as suspicious prior to 2007, the only orders that it identified as suspicious were those that exceeded what were otherwise arbitrary thresholds that were set well above the average for most of AmerisourceBergen's customers.

180. However, during a deposition taken in the MDL, AmerisourceBergen's corporate representative, Chris Zimmerman's description of the company's "two-step process,"[60] made clear that the two steps were not to report suspicious orders and then halt them. Instead, Zimmerman explained that this monthly, after-the-fact report was produced to "send to DEA" while order filers subjectively decided which were suspicious.[61] Thus, notwithstanding its written policies, Zimmerman testified that, in practice, AmerisourceBergen would only report suspicious orders only *after* they were shipped. Zimmerman further testified that this remained the standard protocol until 2007, following the suspension of AmerisourceBergen's Orlando, Florida distribution facility.

181. Sales representatives' on-the-ground observations also were not applied to report and halt suspicious orders, as evidenced by the record in proceedings against one of its Ohio customers. There, an AmerisourceBergen sales representative testified that "the purpose of her visits was not 'to observe [the pharmacist]' in the practice of pharmacy but to get his business." She received no training in identifying or reporting concerns about suspicious activities, or about how to ensure that only legitimate accounts were signed up and maintained.

182. Thus, in practice, even the updated 2012 policies failed to properly monitor for and prevent diversion. AmerisourceBergen still shipped orders shortly after they were reported as

[60] Zimmerman Dep. at 108:5-109:10, August 3, 2018
[61] *Id.*

suspicious, without any evidence that an investigation had cleared the suspicion, as illustrated by the examples described in this Complaint.

183. Further, in the MDL, AmerisourceBergen's corporate representative testified that until 2005, AmerisourceBergen's only due diligence was limited to checking the customer license and DEA registration.

184. In August of 2015, an audit by FT1 Consulting, Inc., whom AmerisourceBergen engaged to review its OMP, found glaring deficiencies. These included a lack of resources, lack of formal training, employees who felt overburdened by their workload and administrative demands, inconsistent policies, and communications breakdowns. Even though "regulatory obligations related to diversion control" were among the "Gaps & Risks" identified in the audit, AmerisourceBergen took no action, and made no changes, in response to the report, according to MDL testimony by its senior director of Diversion Control.

3. *AmerisourceBergen Failed to Maintain Effective Controls Against Diversion in South Carolina.*

185. AmerisourceBergen was one of the largest wholesale distributors in South Carolina, and responsible for approximately 8.2% of the estimated 10 mg equivalent pills distributed in the State from 2006 to 2014— a total of **344,215,266 opioid pills**. Although the data for later years is not available, AmerisourceBergen's market share may have increased because from 2013 forward, AmerisourceBergen became the primary wholesaler supplying Walgreens pharmacies nationally, and Walgreens pharmacies purchased approximately 9% of the estimated 10 mg equivalent pills ordered by South Carolina buyers from 2006 to 2014.

186. Examples of potential red flags of diversion and suspicious orders related to AmerisourceBergen are included in Appendix A.

187. In sum, all Defendants disregarded their obligations under South Carolina law to report suspicious orders and prevent diversion. Instead, they grossly over-supplied opioids into the State and consistently failed to report or suspend illicit orders, deepening the toll of opioid abuse, addiction, and death in South Carolina.

B. DEFENDANTS HAD FINANCIAL INCENTIVES TO DISTRIBUTE AND SELL EVER HIGHER VOLUMES OF OPIOIDS, AND TO REFRAIN FROM REPORTING AND HALTING SUSPICIOUS ORDERS.

188. Distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes of opioid sales and distribution may decrease the cost paid per pill by distributors. Decreased cost per pill, in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, increased sales volumes result in increased profits.

189. Upon information and belief, Defendants also rewarded their sales representatives for increased sales, including the sales of opioids.

C. TO PROTECT THEIR PROFITS, DEFENDANTS LOBBIED AGAINST RESTRICTIONS ON OPIOID USE AND DEA ENFORCEMENT.

190. In April 2016, several members of Congress aligned with the major drug distributors, including Defendants, to pass a law that weakened DEA enforcement against distributors. The new law, the Ensuring Patient Access and Effective Drug Enforcement Act, "imposed a dramatic diminution of the agency's authority," wrote DEA Chief Administrative Law Judge John J. Mulrooney II. It is now "all but logically impossible" for the DEA to stop suspicious narcotic shipments from companies.[62] "The drug industry, the manufacturers, wholesalers,

[62] Scott Higham and Lenny Bernstein, The Washington Post, *The Drug Industry's Triumph Over the DEA*, (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.f12a0ab29856.

distributors and chain drugstores, have an influence over Congress that has never been seen before," said Rannazzisi. "I mean, to get Congress to pass a bill to protect their interests in the height of an opioid epidemic just shows me how much influence they have."

D. DEFENDANTS DELAYED A RESPONSE TO THE OPIOID CRISIS BY PRETENDING TO COOPERATE WITH LAW ENFORCEMENT.

191. Despite their conduct in flooding South Carolina and other states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

192. For example, Cardinal has claimed to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." In its Standards of Business Conduct, Cardinal claims to be "committed to maintaining the integrity of the supply chain by developing and maintaining processes to help guard against diversion. We maintain 'know your customer' policies and procedures to validate that products we ship are sold in accordance with legal and contract requirements and are received by customers for their legitimate use."[63] Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[64]

193. In a 2017 shareholder document, Cardinal published its Opioid Anti-diversion Program and Board Oversight, in which the company noted its role in "maintaining a vigorous program to prevent opioid pain medications from being diverted to improper use."[65] During an earnings call that year, Cardinal's Chairman and Chief Executive Officer, George Barrett,

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[63] 2009 Cardinal Health, *Standards of Business Conduct*, at 30.

[64] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[65] Cardinal Health Proxy, Form 14A at 7, filed Oct. 23, 2017.

promised that Cardinal "operate[s] a very strong, robust, suspicious order monitoring system and process that not only meets our regulatory requirements, we believe it exceeds what is required of distributors." One year later, Barrett returned to the same themes, describing Cardinal's "anti-diversion systems and controls" as "substantial," "well-funded," and "best in class."[66]

194. Cardinal continues to hold itself out as an industry leader, claiming on its website that it implements "state-of-the-art controls to combat the diversion of pain medications from legitimate uses."[67] McKesson's website touts its CSMP, which "uses sophisticated algorithms designed to monitor for suspicious orders, block the shipment of controlled substances to pharmacies when certain thresholds are reached and ultimately report those suspicious orders to the DEA."[68]

195. This misleading self-promotion is not new. In an October 2, 2008 press release, Cardinal Chairman and CEO, R. Kerry Clark, stated:

> Since November 2007, Cardinal Health has invested more than $20 million to significantly enhance its controls across its network to prevent the diversion of controlled substances and has worked diligently with the DEA to resolve the suspensions. Specifically, the company has expanded its training, implemented new processes, introduced an electronic system that identifies and blocks potentially suspicious orders pending further investigation, and enhanced the expertise and overall staffing of its pharmaceutical distribution compliance team.[69]

196. In a 2012 press release, Cardinal again discussed its advanced anti-diversion system and stated:

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[66] Cardinal Health Quarterly Earning Call Transcript at 4, dated Nov. 6, 2017.
[67] Cardinal's website, Addressing the Opioid Crisis: Board Engagement and Governance, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance/board-engagement-and-governance.html.
[68] McKesson's website, About McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program.
[69] *Id.*

> Cardinal Health has robust controls and performs careful due diligence. The company's controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the company's program raises a red flag, its teams immediately investigate. Cardinal Health's anti-diversion specialists use their professional judgment and expertise to determine the appropriate action. The anti-diversion specialists are authorized to stop shipments, investigate further and when appropriate, report matters to the DEA who licenses pharmacies to sell controlled substances.[70]

197. Along the same lines, in 2005, McKesson's "Corporate Citizenship Report" touted the company's "compliance and integrity," claiming:

> Rigorous, unwavering compliance with laws and regulations is the foundation for economic performance and customer and shareholder value creation. McKesson focuses intensely on systems and processes that enable full compliance with the laws and regulations that govern our operations . . . . We are especially aware of our responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety. We provide our customers the complete range of pharmaceuticals approved for use by the FDA, and apply all necessary controls governing the distribution of these substances.[71]

198. McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Its website offers assurances that the company's Controlled Substances Monitoring Program ("CSMP") "uses sophisticated algorithms designed to monitor for suspicious orders, and block the shipment of controlled substances." McKesson also publicly claims that it has a "best-in-class

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[70] *Cardinal Health Inc. Seeks Restraining Order to Avoid Disruption in Controlled Medicine Shipments from Florida*, Feb. 3, 2012, *available at* https://ir.cardinalhealth.com/news/press-release-details/2012/Cardinal-Health-Inc-Seeks-Restraining-Order-to-Avoid-Disruption-in-Controlled-Medicine-Shipments-from-Florida/default.aspx.

[71] McKesson Corporate, *Citizenship Report 2005*, *available at* https://www.slideshare.net/finance2/mckesson-corporate-citizenship-report-74m-2005.

controlled substance monitoring program to help identify suspicious orders," and that it is "deeply passionate about curbing the opioid epidemic in our country."

199. Similarly, AmerisourceBergen's website touts the company's order monitoring program as having "sophisticated technology that tests every controlled substance order against established governing criteria. Orders exceeding those criteria are redirected to experienced diversion control personnel for further analysis and possible cancellation."[72]

200. AmerisourceBergen further contends that it performs "extensive due diligence on customers who intend to purchase controlled substances from us and vetting discovered information through a best-in-class diversion control team of internal and external experts before granting them permission to purchase." [73]

201. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade association, the HDMA (now HDA), filed an amicus brief in Masters Pharmaceuticals, which made the following statements:[74]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

202. Through the above statements and others, Defendants not only acknowledged that they understood their obligations under the law, but created the false and misleading impression that their conduct was in compliance with those obligations.

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72 AmerisourceBergen's website, Fighting the Opioid Epidemic, Ensuring Sage and Secure Drug Distribution, https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.

73 *Id.* (AmerisourceBergen's website, Fighting the Opioid Epidemic)

74 Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

E. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct

203. The State continues to suffer harm from Defendants' unlawful actions.

204. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity has not ceased. The public nuisance remains unabated, as does the conduct causing the nuisance.

2. Equitable Estoppel and Fraudulent Concealment

205. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the State and to purposefully conceal their unlawful conduct and fraudulently assure the public, including state governments, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor and dispenser status in South Carolina and continuing to generate profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, and the State, that they are working to curb the opioid epidemic.

206. Defendants were deliberate in taking steps to conceal their active role in the oversupply of opioids and their failure to prevent the entry of prescription drugs into illicit markets, which fueled the opioid epidemic.

207. As set forth herein, Defendants concealed the existence of the State's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances

that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the State, and deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims.

208. The State did not discover the nature, scope, and magnitude of Defendants' misconduct until recently, and its full impact on the State, and the State could not have acquired such knowledge earlier through the exercise of reasonable diligence.

209. Defendants thus successfully concealed from the public, and the State, facts sufficient to arouse suspicion of the claims that the State now asserts.

F. THE DEVASTATING EFFECTS OF THE OPIOID CRISIS IN SOUTH CAROLINA

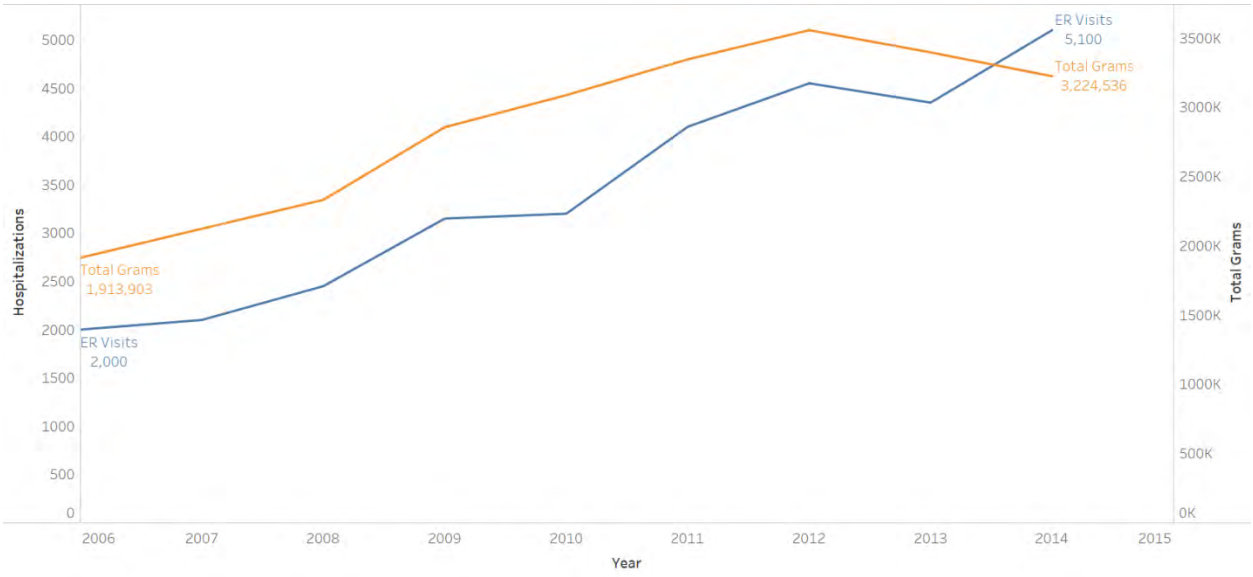
210. While manufacturers overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use, Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into South Carolina that they could only have been delivering a significant portion of those opioids for diversion and illicit use. The disproportionate volume of opioids that flooded into South Carolina as a result of Defendants' wrongful conduct has devastated the state.

211. Had Defendants established and implemented programs to prevent diversion and identified, reported, and rejected suspicious orders, the supply of opioids would not have been as great, and fewer opioids would have been available for diversion and improper use. The use and

abuse of these opioids resulted in the epidemic of addiction, overdose, and death that have wracked South Carolina.

212. As the total grams of opioids shipped to South Carolina increased from 2006 to 2014, so did the opioid-related emergency room visits and hospitalizations. Beginning, in 2006, emergency room admissions for opioid-related causes appeared to increase steadily as well.

Opioids Related Hospitalizations and Total Grams Overtime
(Confidential ARCOS; Healthcare Cost and Utilization Project (HCUP): 2006-2014, South Carolina)

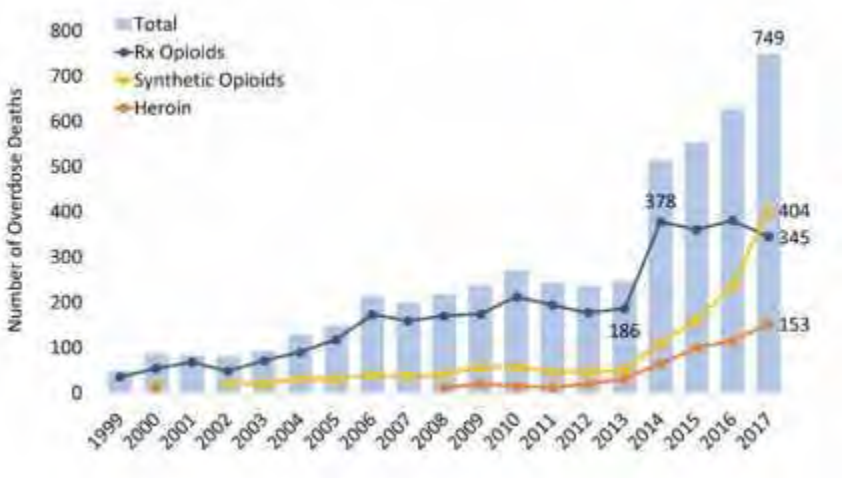


213. The same was true of inpatient hospitalizations. In 2017, 6,961 people in South Carolina were discharged from emergency and inpatient departments after receiving treatment for opioid overdoses or poisoning.

214. South Carolina deaths related to opioids have dramatically increased, as described above.[75]

[75] The graph above is prepared by the National Institute on Drug Abuse, which notes that it depicts the "Number of overdose deaths involving opioids in South Carolina, by opioid category. Drug categories presented are not mutually exclusive, and deaths might have involved more than one substance. Source: CDC WONDER." *Available at,* https://www.drugabuse.gov/opioid-summaries-by-state/south-carolina-opioid-summary

Number of Overdose Deaths Involving Opioids in South Carolina
(National Institute on Drug Abuse; Opioid-Involved Overdose Deaths;South Carolina Opioid Summary Revised March 2019)



215. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[76]

216. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Prescription opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. The number of deaths from prescription and illicit opioid overdoses in South Carolina surpassed the number of homicides. Greenville County saw 95 overdoses in 2015, compared to 11 homicides in the same year. Many others are swept into a cycle of addiction and abuse with which they will struggle their entire lives.

217. Not only did Defendants' systemic failures and disregard for the law extend to orders shipped directly into South Carolina, they impacted the State through diversion from other areas as well. For example, a criminal indictment of a couple accused of operating a particularly

[76] Theodore J Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban*, *and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

prolific pill mill in Ohio alleged that the couple's illicit prescriptions fueled trafficking and addiction not only in Ohio, but also in South Carolina and other states. Moreover, Florida was well known for its role in supplying opioids to so-called "prescription tourists," who would stock up on pills and return to other states to sell them. The route between Florida and other states became so well-traveled that it was colloquially known as the "OxyContin Express" or "Blue Highway," named after opioid pills made by Purdue and another manufacturer, Mallinckrodt, respectively. The I-95 corridor, which runs from Florida through South Carolina, was a prominent transport route for prescription pills. As one US attorney explained the situation: "In some cases, prescriptions are being written by doctors in places such as Middle Georgia and filled in . . . South Carolina."[77]

218. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend.

219. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. In South Carolina, administrations of naloxone (or Narcan) rose from 4,187 in 2015 to 6,427 in 2016. In Horry County alone, local officials used *Narcan* *over 1,000 times* in 2016. From 2013 to 2018, the State has seen a 110% increase in naloxone administrations to reverse opioid overdoses by EMS personnel throughout the state

[77] Halimah Abdullah, *"Pill Mill Pipeline" Creeping into Rural Georgia*, Macon Telegraph (Mar. 14, 2011), https://www.mcclatchydc.com/news/nation-world/national/article24616633.html.

220. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with prescription painkiller use. Nearly half of surveyed men not in the labor force said they took painkillers daily, and two-thirds of them were on prescription medications—compared to just 20% of employed men who reported taking painkillers. Many of those taking painkillers still said they experienced pain daily.

221. The abuse of opioids has injured South Carolina residents in other respects. The number of chronic Hepatitis C in South Carolina cases has almost doubled since 2011 to over 6,400 in 2018. The increase is largely a result of intravenous drug use stemming from the opioid epidemic.

222. Oversupply of opioids also had a significant detrimental impact on children in South Carolina. There has been a dramatic rise in the number of infants who are born dependent on opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from opioids once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

223. In South Carolina, the incidence of NAS quadrupled between 2000 and 2013 from roughly 1 infant per 1,000 hospital births to 4 per 1,000, which would amount to 221 infants in

2013. South Carolina Vital Statistics reported in 2016, inpatient births in the state to be 51,925, of those births, 219 were born with NAS and in need of treatment. In 2017, 264 babies were born with NAS in South Carolina. Typically, a newborn baby will spend on average 2.1 days in the hospital; however, a baby born with NAS averages a 16.9 day stay in the Neonatal Intensive Care Unity (NICU) at a cost of $3,946.74 per day.

224. Children are also injured by the dislocation caused by opioid abuse and addiction. The number of South Carolina children removed from homes with substance abuse nearly doubled from 397 in the year ending August 2011 to 634 in the year ending August 2016. In 2016, the South Carolina Department of Social Services reported 634 children entered into foster case due to a parent's drug abuse. By 2017, the number of children entering into foster care because of a parent's drug abuse rose to 648. A parent's drug abuse remains the third highest reason in South Carolina for a child to enter foster care, behind neglect and physical abuse.

225. Opioids now outpace other sources of addiction in demand for substance abuse treatment.

226. As described above, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Roughly 80% of heroin users previously used prescription opioids. Greenville County Sheriff Will Lewis has called heroin addiction a "pandemic," and reports that opioids now account for 43% of all fatal drug overdoses in the county.[78] A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into South Carolina communities and taking the

[78] Greenville's opioid problem was brought to forefront at public hearing; https://www.greenvilleonline.com/story/news/2017/07/13/greenvilles-opioid-problem-brought-forefront-public-hearing/469547001/.

lives of individuals previously addicted to prescription opioids who turned to heroin and now heroin laced with fentanyl. In South Carolina, fentanyl overdose deaths rose from 68 in 2014 to 362 in 2017, and again to 460 fatal overdoses from fentanyl in 2018.

V. CLAIMS FOR RELIEF

COUNT I

FOR A FIRST CAUSE OF ACTION

SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT – UNFAIR ACTS AND PRACTICES

227. The State incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

228. Under SCUTPA, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." S.C. Code Ann. § 39-5-20(a).

229. South Carolina courts define an "[u]nfair trade practice" as "a practice which is offensive to public policy or which is immoral, unethical, or oppressive." *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 414 S.C. 33, 56-57, 777 S.E.2d 176, 188 (S.C. 2015) (internal quotation marks omitted). "Whether an act or practice is unfair or deceptive within the meaning of SCUTPA depends upon the surrounding facts and the impact of the transaction on the marketplace." *Id.*, 414 S.C. 56-57 (internal quotation marks and alteration omitted).

230. At all times relevant to this Complaint, Defendants were engaged in the trade or commerce of distributing and selling prescription opioid pain medications. Each is a leading force in the prescription opioid market in South Carolina.

231. At all times relevant to this Complaint, Defendants violated SCUTPA by engaging in unfair acts or practices in distributing and selling opioids in South Carolina. These acts or

practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to South Carolina consumers.

232. Defendants' unfair and deceptive acts or practices include, but are not limited to, failing to maintain effective controls against opioid diversion by:

a. Oversupplying opioids into South Carolina;

b. Failing to create, maintain, and/or use a compliance program that maintains effective controls against the diversion of opioids;

c. Failing to report suspicious reports of controlled substances;

d. Shipping suspicious orders for prescription opioids; and

e. Failing to exercise due diligence to ensure that customers could be trusted with opioids.

233. These acts and practices were particularly immoral, unethical, oppressive, or unscrupulous, and offensive to public policy in that they were undertaken while Defendants were publicly professing commitment to combating the opioid epidemic and claiming to use advanced analytics and technology to address suspicious orders and prevent illegitimate use of prescription opioids while they were actually failing to maintain effective controls against diversion.

234. These acts or practices offend established public policies including:

a. The policy, reflected in both the SCCSA and federal law, as well as their implementing regulations, which require the monitoring and reporting of suspicious orders of controlled substances. By failing to monitor, detect, report, investigate, and refuse to fill suspicious orders as required by these laws, Defendants also failed to minimize the risk of diversion of controlled substances to unlawful use; and

b. The State's efforts, across multiple branches of government, to combat the opioid epidemic, including nine laws passed in 2018 alone.

235. These acts or practice were also unfair in that they offended established public policy, reflected in the State's Constitution, that "[t]he health, welfare, and safety of the lives and

property of the people of this State and the conservation of its natural resources are matters of public concern." S.C. Const. art. XII, § 1.

236. Defendants' conduct has caused substantial injury in the State—in lives lost to drug overdoses, addictions endured, emergency room visits, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

237. The profound injuries to the State are not outweighed by any countervailing benefits to consumers or competition. Particularly in light of Defendants' lack of transparency and public claims of commitment to exercising due diligence not to fuel abuse and diversion of prescription opioids, and given the addictive nature of opioids, consumers could not reasonably have avoided their injuries.

238. Defendants' acts and practices as alleged herein substantially impacted the community of patients, health care providers, and the public, and caused significant actual harm.

239. Defendants' acts and practices as alleged herein were motivated by a desire to retain and increase their market share and profits. Their conduct in deliberately disregarding their obligation to maintain effective controls against diversion and to report and halt suspicious orders, as well as their conduct in misrepresenting and concealing the truth, reflects a corrupt corporate culture that persisted over many years.

240. Defendants' misconduct was substantial, and the acts and practices regarding South Carolina consumers as alleged in this Complaint were undertaken in bad faith. These acts or practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that Defendants deliberately disregarded obligations meant to protect the public health and safety.

241. At the time they engaged in the conduct described in this Complaint, defendants knew should have known that they were fueling an illicit market for dangerous drugs.

242. At all times Defendants knew or should have known that their conduct violated the South Carolina Unfair Trade Practices Act and therefore is willful for purposes of S.C. Code § 39-5-110, justifying civil penalties.

243. Defendants' acts and practices regarding South Carolina consumers as alleged herein are capable of repetition and affect the public interest.

244. This action seeks to protect the citizens of South Carolina from unfair acts in the conduct of trade and commerce.

245. Defendants' acts or practices alleged herein constitute unfair acts or practices in violation of S.C. Code § 39-5-20.

246. Every unfair act by Defendants constitutes a separate and distinct violation of S.C. Code § 39-5-20.

COUNT II

FOR A SECOND CAUSE OF ACTION

PUBLIC NUISANCE

247. The State incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

248. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

249. Defendants, through the actions described in the Complaint, have created—or were a substantial factor in creating— a public nuisance by unreasonably interfering with a right

common to the general public that works hurt, inconvenience, or injury and interferes with the enjoyment of life or property.

250. Defendants' acts and omissions, as described above, involve a significant interference with the public health, safety, the public peace, the public comfort or the public convenience, and unreasonably interfere with a public right by creating a public health epidemic in South Carolina.

251. Here, Defendants' conduct is governed by statutes and regulations, including the South Carolina Controlled Substances Act and the federal CSA and regulations incorporated therein.

252. Defendants engaged in conduct in violation of the SCCSA by failing to maintain effective controls against diversion and failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and stop shipping suspicious orders of opioids.

253. Defendants' conduct is of a continuing nature and has produced a permanent or long-lasting effect on the public right which was foreseeable to Defendants

254. Each Defendant is liable for creating the public nuisance because the unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to the State.

255. Defendants knew or should have known that their failure to comply with their statutory and common law duties to maintain effective controls against diversion, including by monitoring, reporting, and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.

256. Defendants also knew or should have known that their conduct, as described in this Complaint, would create or assist in the creation of a hazard to public health and safety and a public nuisance.

257. Defendants' conduct created or increased an unreasonable risk of harm.

258. Defendants' conduct is unreasonable, intentional, reckless, and/or negligent, and unlawful.

259. Prescription opioids are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are regulated as controlled substances under federal and state law as a result of their high potential for abuse and severe addiction.

260. The opioid epidemic has received widespread publicity and Defendants' own surveillance and information demonstrated the widening toll of opioid addiction, overdose, hospitalizations, and fatalities, first in specific regions and then across the country.

261. The injury inflicted by Defendants was of a type that a reasonable controlled-substances distributor would foresee as a likely result of its conduct.

262. The public nuisance is substantial and unreasonable. Defendants' actions caused, and continue to cause, the public health epidemic described in this Complaint.

263. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the State described herein.

264. Each Defendant's actions were, at the very least, a material element and substantial factor in bringing about the injury. Each Defendant's actions were, at the very least, a material element and substantial factor in opioids becoming widely available and widely used in the state. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without each Defendant's actions, opioid use,

misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or much less severe.

265. The nuisance created by Defendants' conduct is abatable.

266. The opioid epidemic is unprecedented in terms of its impact on the State of South Carolina.

267. The State seeks all equitable relief as allowed by law, including, *inter alia*, injunctive relief and abatement of the public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

VI. PRAYER FOR RELIEF

WHEREFORE, the State requests the following relief:

268. A finding that by the acts alleged herein, Defendants engaged in unfair acts and practices in the course of engaging in trade or commerce within South Carolina in violation of S.C. Code § 39-5-20;

269. An injunction pursuant to S.C. Code § 39-5-50 permanently enjoining Defendants from engaging in any acts that violate SCUTPA, including, but not limited to, the unfair acts and practices alleged herein;

270. Civil penalties in the amount of $5,000, pursuant to S.C. Code § 39-5-110(a), for each and every willful violation of SCUTPA;

271. Attorneys' fees and costs pursuant to S.C. Code § 1-7-85 for violations of SCUTPA;

272. A finding that Defendants created a public nuisance;

273. An injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

274. An order directing Defendants to abate the public nuisance;

275. Pre-and post-judgment interest; and

276. Such other and further relief as this Court deems just and equitable.

VII. JURY DEMAND

277. The State demands trial by jury on all issues so triable.

DATED: August 15, 2019

THE STATE OF SOUTH CAROLINA

/s/Alan Wilson

Alan Wilson (S.C. Bar No. 71754)
Attorney General

W. Jeffrey Young (S.C. Bar No. 5747)
Chief Deputy Attorney General

Robert D. Cook (S.C. Bar No. 1373)
Solicitor General

C. Havird Jones, Jr. (S.C. Bar No. 3178)
Senior Assistant Deputy Attorney General
Jared Q. Libet (S.C. Bar No. 74975)
Assistant Deputy Attorney General
Chantelle Neese (S.C. Bar. No. 101292)
Assistant Attorney General
Rebecca McCormack (S.C. Bar No. 101302)
Assistant Attorney General
Annemarie Mathews (S.C. Bar. No. 65171
Assistant Attorney General

OFFICE OF THE ATTORNEY GENERAL
Post Office Box 11549
Columbia, South Carolina 29211
(803) 734-3970

Linda Singer (*pro hac vice* to be submitted)
MOTLEY RICE LLC
401 9th St. NW, Suite 1001
Washington, DC 20004
(202) 232-5504386-9626

Joseph F. Rice (S.C. Bar No. 4710)
Marlon E. Kimpson (S.C. Bar No. 17042)
Jodi Westbrook Flowers (S.C. Bar No. 66300)
Lisa M. Saltzburg (S.C. Bar No. 78505)
Natalie Deyneka (S.C. Bar No. 102230)

Temitope Leyimu (S.C. Bar No. 101288)
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, South Carolina 29464
(843) 216-9000

Karl S. Bowers, Jr.
Bowers Law Office LLC
S.C. Bar No. 16141
P.O. Box 50549
Columbia, South Carolina 29250
Telephone: (803) 753-1099
Telecopier: (803) 250-3985
butch@butchbowers.com

I.S. Leevy Johnson (SC Bar No. 003020)
George C. Johnson (SC Bar No. 9308)
1615 Barnwell Street
Post Office Box 1431
Columbia, South Carolina 29202
(803) 252-9700
islj@jtbpa.com
george@jtbpa.com

James W. Fayssoux, Jr., SC Bar # 16659
FAYSSOUX AND LANDIS, P.A.,
P.O. Box 10207
Greenville, SC 29603
(864) 233-0445 phone
(864) 672-3706 fax
wally@fayssouxlaw.com

J. Stephen Schmutz
SC Bar No. 4974
Schmutz & Schmutz, PA
24 Broad Street
Charleston, SC 29401
843-577-5530
843-577-9204 facsimile
steve@schmutzlaw.com

Exhibit A

SETTLEMENT AND RELEASE AGREEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2nd day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

BACKGROUND

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Denver, Colorado distribution center (the "Denver Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson has failed to report suspicious orders of controlled substances and to report thefts or significant losses of controlled substances as more fully set forth in Appendix B, Paragraph 8 as required by 21 C.F.R. 1301.74(b); and

WHEREAS, McKesson is registered with DEA at 39 facilities as distributors of Schedule II-V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention Control Act of 1970, Title 21 U.S.C. § 801 et seq., ("CSA" or "the Act"); and

WHEREAS, McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports; and

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the Orders and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

2. No Admission or Concession. This Agreement is neither an admission by McKesson of liability or of any allegations made by DEA in the Orders and investigations, nor a concession by DEA that its allegations in the Orders and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

(i) the conduct alleged in the Orders;

(ii) the alleged failure of McKesson to maintain adequate controls against the diversion of controlled substances, on or prior to December 31, 2007, at all distribution facilities operated, owned, or controlled by it;

(iii) the conduct described in Appendix B, Paragraph 8 to this Agreement; and

(iv) the alleged failure of McKesson to detect and report suspicious orders of the controlled substances as required by 21 C.F.R. § 1301.74(b) on or before December 31, 2007.

4. DEA Headquarters. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.

5. McKesson Representative. For purposes of this Agreement, the McKesson Representative shall be the Senior Vice President, Distribution Operations or the Vice President, Regulatory Affairs.

II. Terms and Conditions

1. *Obligations of McKesson*.

(a) McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions. McKesson acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

(b) Within five (5) business days following the date of each controlled substance transaction, McKesson shall provide DEA Headquarters with a report of all controlled substance transactions through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and thus does not contain any adjustments or corrections that would normally be part of McKesson's reconciliation of its business records. The Parties agree that the report does not

otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). McKesson shall begin transmitting this information no later than 120 days after the Parties have mutually agreed upon a format. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

(c) McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, McKesson shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.

(d) McKesson agrees to a temporary suspension of its authority to distribute drugs containing the drug codes for Schedule III hydrocodone combination products and alprazolam, that is, DEA drug codes 9805, 9806 and 2882 with respect to the DEA registrations for its Lakeland Facility and its Conroe Facility, except for sales to the accounts as listed in Appendix C. The temporary suspension shall terminate in accordance with subsection II.2(g) unless sooner terminated by the Parties in writing pursuant to the terms of this Agreement.

(e) McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to McKesson's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

(f) McKesson agrees that within 120 days of the Effective Date of this Agreement it will review distributions of hydrocodone and alprazolam for the 24-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of hydrocodone and alprazolam exceeded the thresholds established in its compliance program. McKesson shall conduct an investigation and take appropriate action as required by this Agreement, DEA regulations and other procedures established under McKesson's compliance program including its Controlled Substance Monitoring Program (CSMP).

(g) McKesson's policy and procedure is to cooperate with the government in any investigation. McKesson agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any

pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party.

(h) McKesson agrees to pay civil penalties to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of $13,250,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and for failing to report thefts or significant losses of controlled substances. Payment of said civil penalties shall be made by McKesson in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix B, Paragraph 13. McKesson agrees to execute the Settlement Agreement at Appendix B simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said civil penalties within 30 days of the Effective Date of this Agreement.

(i) Any material breach by any McKesson facility of subsections II.1(a)-(h) of this Agreement by McKesson after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of McKesson's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

(a) At McKesson's request, DEA shall continue to provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members at McKesson trade shows and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

(b) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II.1(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

(c) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to this customer.

(d) DEA agrees that any request made by DEA or any of its employees that McKesson continue to sell controlled substances to customers for an order that McKesson has determined to be suspicious shall be made in writing to the designated McKesson Representative.

(e) Within 150 days of the Effective Date of this Agreement, but not earlier than 90 days after the Effective Date of this Agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program ("Compliance Reviews") at up to eight distribution centers of McKesson, consisting of the Lakeland Facility; the Landover Facility; the Conroe Facility; and five other McKesson distribution centers selected by DEA. DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify McKesson no less than 48 hours prior to commencing a Compliance Review at a distribution center. DEA shall issue a Notice of Inspection to McKesson upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the Compliance Review.

(f) The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to McKesson on or before 165 days from the Effective Date of Agreement, stating that McKesson failed to meet any of the requirements in either subsections II.2(f)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with McKesson within 48 hours regarding such a finding. DEA shall consider remedial measures that McKesson has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

(g) Upon the completion of the Compliance Reviews and within 180 days of the Effective Date of this Agreement, DEA will restore the drug codes 9805, 9806 and 2882 to the DEA registrations for the Lakeland and Conroe Facilities. In the event that McKesson has not satisfied DEA in regard to the Compliance Reviews within 180 days of the Effective Date of this Agreement and DEA issues a Show Cause against either of the Lakeland or Conroe Facilities, McKesson agrees to a new period of suspension of the drugs codes at such facility until the matter is resolved by mutual agreement of the Parties or a final decision by the DEA Deputy Administrator. Notwithstanding, nothing in this Agreement shall prevent the Parties from agreeing to an extension or shortening of the suspension period for these drugs codes at the Lakeland and Conroe Facilities at any time during the course of this Agreement. DEA shall not be prevented from taking any action that would otherwise be available to the agency to pursue a new period of suspension of the drug codes at these facilities.

(h) DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.

(i) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement; all actions taken by McKesson pursuant to this Agreement; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility and at other McKesson facilities.

(j) DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to December 31, 2007, which may allege that McKesson failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by McKesson to DEA on or before December 31, 2007 for indications that McKesson may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix B, Paragraph 8) occurring before December 31, 2007, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

3. Joint Obligations of the Parties. McKesson and DEA agree that upon the execution of this Agreement, DEA and McKesson shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Lakeland Facility and Landover Facility.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

(i) Release McKesson from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders; and

(ii) Refrain from filing any administrative claims against McKesson within DEA's enforcement authority under21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of December 31, 2007, and the review of the reports and records McKesson submitted to DEA prior to December 31, 2007.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement

agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that McKesson's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

(a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

(c) Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) five (5) business days after the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction. However, the Parties agree to provide each other with advance notice the day before or as soon as possible once a decision has been made to issue any public statement or press release related to this Agreement. The Parties shall provide copies of any press release no later than two hours before issuing the press release. This paragraph does not apply to any press release or public statement issued by the Department of Justice or any United States Attorney's Office. This paragraph shall remain in effect for sixty (60) days, commencing with the Effective Date of the Agreement.

7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

8. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

9. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the McKesson distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

MCKESSON CORPORATION

By: _____
John H. Hammergren
President
McKesson Corporation

Dated: April 28, 2008

By: _____
Donald G. Walker
Senior Vice President
McKesson Corporation

Dated: April 30, 2008

THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

By: _____
Michele M. Leonhart
Acting Administrator
Drug Enforcement Administration

Dated: May 2, 2008

By: _____
Wendy H. Goggin
Chief Counsel
Drug Enforcement Administration

Dated: May 1, 2008

Appendix A

McKesson Distribution Center DEA Registered Facilities

Location	(b)(4)
Carol Stream, IL	
Methuen, MA	
West Seneca, NY	
Everett, WA	
Anchorage, AK	
Aurora, CO	
Livonia, MI	
Honolulu, HI	
Santa Fe Springs, CA	
Duluth, GA	
Memphis, TN	
Washington Ct. House, OH	
Oklahoma City, OK	
La Vista, NE	
Tolleson, AZ	
Wilsonville, OR	
La Crosse, WI	
Delran, NJ	
Salt Lake City, UT	
West Sacramento, CA	
O'Fallon, MO	
Memphis, TN	
Lakeland, FL	
New Castle, PA	
Landover, MD	
Aberdeen, SD	
Conroe, TX	
McCalla, AL	
Little Canada, MN	
Cape Girardeau, MO	
Rocky Hill, CT	
Aurora, CO	

Appendix B

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this 30th day of April, 2008, by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of Maryland, Middle Florida, Southern Texas, Colorado, Utah and Eastern California ("United States") and McKesson Corporation including facilities doing business as McKesson Pharmaceuticals and McKesson Drug Company, ("McKesson") and collectively referred to as "the Parties."

RECITALS

1. McKesson is a Delaware corporation and is headquartered in San Francisco, California. Among other things, McKesson is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, McKesson operates numerous distribution facilities in the United States, including six facilities more fully described in Attachment A to this Agreement ("the Six Facilities").

2. As more fully described in Attachment A, McKesson holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from these facilities including the Six Facilities.

3. McKesson is required to operate the Six Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").

4. Each of the Six Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective

jurisdictions as stated in Paragraph 8.

5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.

6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).

7. Methadone, Hydrocodone, Phentermine, Fentanyl and Oxycodone are medications whose manufacture, distribution, sale and possession are regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term ~~is defined under 21~~ *C.F.R. §1301.74(b).*

8. The "Covered Conduct" shall mean the following alleged conduct:

A. Within the District of Maryland: From January 2005 through October 2006, McKesson-Landover sold approximately 3 million dosage units of hydrocodone to NewCare Pharmacy in Baltimore, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). Further, from August 2006 to February 2007, McKesson-Landover sold large quantities of phentermine based products to Smeeta Pharmacy *in Highland, Maryland and failed to report these sales as suspicious* orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

B. Within the Middle District of Florida: In October 2005, McKesson-Lakeland sold approximately 2.1 million dosage units of hydrocodone to seven pharmacies in the Tampa area (Trelles Pharmacy, BiWise Drugs, Universal RX, United Prescription Service, Accumed Rx Medipharm RX and Avee Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

C. Within the Southern District of Texas: From February to September 2007, McKesson-Conroe sold approximately 2.6 million dosage units of hydrocodone to Mercury Drive Pharmacy and Maswoswe's Alternative Pharmacy and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

D. Within the District of Colorado: From September 2005 through November 2007, McKesson-Aurora sold large quantities of hydrocodone to three Colorado pharmacies (Brighton Pharmacy in Brighton, Colorado; Western States Pharmacy in Brighton, Colorado; and St. Vrain's Pharmacy in Lyons, Colorado), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

E. Within the District of Utah: From January 2005 through October 2007, McKesson-Salt Lake City sold approximately 824,000 dosage units of hydrocodone, Oxycodone, Fentanyl and Methadone to the Blackfeet Clinic in Browning, Montana, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

F. Within the Eastern District of California: From October 2007 through June 2007, McKesson-West Sacramento suffered the theft or significant loss of controlled substances on twenty-eight separate occasions, and failed to timely submit required theft and loss reports to DEA, in violation of 21 C.F.R. §§ 1301.74(c) and 1301.76(b), and 21 U.S.C. § 842(a)(5).

9. By entering into this Agreement, McKesson does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing. McKesson explicitly denies any allegations of violations of the CSA or DEA regulations and represents that the company has defenses to the violations alleged by the government.

10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)), authorized the imposition of a civil penalty of up to $25,000 for each violation of the Section, except that violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to $10,000 for each violation.

11. To avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against McKesson under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by McKesson nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

TERMS AND CONDITIONS

13. McKesson shall pay to the United States the sum of Thirteen Million, Two Hundred Fifty Thousand Dollars ($13,250,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:

A. For Conduct Alleged to have Occurred within the District of Maryland: McKesson shall pay the sum of Two Million Dollars ($2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Maryland, pursuant to instructions provided by the United States.

B. For Conduct Alleged to have Occurred within the Middle District of Florida: McKesson shall pay the sum of Seven Million Four Hundred Fifty-Six Thousand Dollars ($7,456,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.

C. For Conduct Alleged to have Occurred within the Southern District of Texas: McKesson shall pay the sum of Two Million Dollars ($2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.

D. For Conduct Alleged to have Occurred within the District of Colorado: McKesson shall pay the sum of One Million Dollars ($1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.

E. For Conduct Alleged to have Occurred within the District of Utah: McKesson shall pay the sum of Five Hundred Forty-Four Thousand Dollars ($544,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Utah, pursuant to instructions provided by the United States.

F. For Conduct Alleged to have Occurred within the Eastern District of California: McKesson shall pay the sum of Two Hundred Fifty Thousand Dollars ($250,000). Payment shall be by electronic funds transfer to the United States Attorney's Office,

Eastern District of California, pursuant to instructions provided by the United States.

14. In consideration of the undertakings by McKesson, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842(c)(1) against McKesson, its officers, directors, and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

15. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:

A. Any potential criminal liability;

B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);

C. Any administrative liability, including mandatory exclusion from any federal programs;

D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and

E. Any claims based on such obligations as are created by this agreement.

17. McKesson acknowledges that each of its DEA registered facilities is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken good-faith actions to detect and prevent

diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA dated May 2, 2008.

18. McKesson agrees that any and all costs it has or will incur in connection with this matter--including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action--shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between McKesson and an Office of the United States Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal judicial district of the Office with whom the dispute arose, and to the extent that state law applies to the dispute, the law of the State within the jurisdictional district shall apply. If a dispute arises under this Agreement between McKesson and more than one of the United States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie in the District of Maryland and to the extent that state law applies to the dispute, the law of Maryland shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot be amended except in writing and when signed by all the Parties to this Agreement.

23. McKesson acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

25. This Agreement shall be effective on the date of signing by all the Parties. It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

On Behalf of McKesson Corporation
One Post Street
San Francisco, California 94104

By: _____
John H. Hammergren
President

Dated: April 28, 2008

By: _____
Donald G. Walker
Senior Vice President

Dated: April 30, 2008

By: _____
John A. Gilbert, Jr.
Hyman, Phelps & McNamara, P.C.
Counsel to McKesson Corporation

Dated: April 25, 2008

On Behalf of the United States

ROD J. ROSENSTEIN
United States Attorney
District of Maryland

By: _____

Michael A. DiPietro
Assistant United States Attorney

Dated: April 21, 2008

Dated: April 29, 2008

ROBERT E. O'NEILL
United States Attorney
Middle District of Florida

By: _____

Javier Guzman
Assistant United States Attorney

Dated: April 21, 2008

DONALD J. DeGABRIELLE
United States Attorney
Southern District of Texas

By: _____

Jill Vernazza
Assistant United States Attorney

Dated: April 22, 2008

TROY A. EID
United States Attorney
District of Colorado

By: _____

Amanda Rocque
Assistant United States Attorney

Dated: April 29, 2008

BRETT L. TOLMAN
United States Attorney
District of Utah

By: _____

Eric A. Overby
Assistant United States Attorney

McGREGOR W. SCOTT
United States Attorney
Eastern District of California

By: _____

Catherine Swann
Assistant United States Attorney

Dated: April 29, 2008

ATTACHMENT A

(Six McKesson Facilities Referenced in Paragraph 1 of this Agreement)

1. 7721 Polk Street in Landover Maryland ("McKesson-Landover"), located within the District of Maryland and operating under DEA registration number PD0029567;

2. 1515 West Bella Vista Street in Lakeland Florida ("McKesson-Lakeland"), located within the Middle District of Florida and operating under DEA registration number PM 0000771;

3. 3301 Pollock Drive in Conroe Texas ("McKesson-Conroe"), located within the Southern District of Texas and operating under DEA registration number RM 0328408;

4. 14500 East 39th Avenue in Aurora Colorado ("McKesson-Aurora"), located within the District of Colorado and operating under DEA registration number PM 0018425;

5. 1900 South 4490 West in Salt Lake City Utah ("McKesson-Salt Lake City"), located within District of Utah and operating under DEA registration number PM0023046; and

6. 3775 Seaport Boulevard in West Sacramento California ("McKesson-West Sacramento"), located within the Eastern District of California and operating under DEA registration number PM 0021535.

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

Exhibit B

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(l), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: 3/05/17

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: 1/5/2017

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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_____
Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

_____
John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

_____
Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

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_____
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Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-3-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
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Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Scheckter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

Exhibit C

SETTLEMENT AND RELEASE AGREEMENT
AND
ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Appendix A to this Agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all Cardinal DEA registered facilities identified in Appendix A.

BACKGROUND

1. Cardinal is registered with DEA at 27 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" of "the Act"). See Appendix A.

2. On November 28, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 801 C Street NW, Suite B, Auburn, Washington 98001 ("Auburn Facility"). See Appendix B.

3. On December 5, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 2045 Interstate Drive, Lakeland, Florida 33805 ("Lakeland Facility"). See Appendix C.

4. On December 7, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 1120 Commerce Boulevard, Swedesboro, New Jersey 08085 ("Swedesboro Facility"). See Appendix D.

5. On January 30, 2008, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause to Cardinal, with respect to its distribution facility located at 13651 Dublin Court, Stafford, Texas 77477 ("Stafford Facility"). See Appendix E.

6. The Orders to Show Cause referenced above alleged, among other things, that Cardinal failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal.

7. DEA also alleges that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located at the following addresses:

a. 500 Jerry Steele Lane, McDonough, Georgia 30253 ("McDonough Facility").

b. 27680 Avenue Mentry, Valencia, California 91355 ("Valencia Facility").

c. 4875 Florence Street, Denver, Colorado 80238 ("Denver Facility").

8. DEA alleges that Cardinal failed to report suspicious orders of controlled substances as more fully set forth in Appendix F, Paragraph 8 as required by 21 C.F.R. § 1301.74(b) .

9. The Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances.

STIPULATION AND AGREEMENT

The facts alleged in the Orders to Show Cause and the facts alleged in paragraphs 7 and 8 above as otherwise summarized above, if proven at an administrative hearing, could constitute grounds for revoking the DEA registrations of the facilities referenced in paragraphs 2-5 and 7 above. In lieu of continuing proceedings to revoke the DEA registrations for the facilities referenced in paragraphs 2-5 and 7 above, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, all outstanding administrative claims and/or issues with respect to the alleged failure of Cardinal to detect and report suspicious orders and the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, including but not limited to the conduct described in the Orders to Show Cause, and all outstanding claims and or issues with respect to the allegations set forth in paragraphs 7 and 8 above. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Cardinal of liability or of the veracity of any allegation made by DEA in the Orders to Show Cause, this Agreement or any investigation, nor a concession by DEA that its allegations in the Orders to Show Cause and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. the conduct alleged in the Orders to Show Cause (Appendices B-E);

b. the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, at all distribution facilities listed in Appendix A operated, owned, or controlled by it;

c. the conduct described in Appendix F, Paragraph 8 to this Agreement; and

d. the alleged failure of Cardinal to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before September 30, 2008.

II. Terms and Conditions

1. Obligations of Cardinal.

a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

b. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). Cardinal shall begin transmitting this information for all controlled substances no later than 90 days after the Parties have mutually agreed upon a format and as soon as practicable

for carisoprodol and tramadol. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

c. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within thirty days of the Effective Date of this Agreement that Cardinal will no longer be required to provide suspicious order reports or any other type of report regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty days written notice.

d. Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement and the Settlement Agreement at Appendix F, whichever is later.

e. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

f. Cardinal agrees that within 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Cardinal's compliance program.

g. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the

rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

h. Cardinal agrees to pay to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) the amount of $34,000,000.00 in settlement of claims or potential claims for civil penalties made by the United States of America for failing to report suspicious orders of controlled substances. Payment of said amounts shall be made by Cardinal in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix F, Paragraph 13. Cardinal agrees to execute the Settlement Agreement at Appendix F simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said amounts within 30 days of the Effective Date of this Agreement.

i. Any material breach by any Cardinal facility of subsections II(1)(a)-(h) of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

a. At Cardinal's request, DEA shall provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members and Cardinal employees at Cardinal trade shows, or at Cardinal internal training sessions, and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II(1)(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

c. Within 150 days of the Effective Date of this Agreement, but not earlier than the later of 90 days after the Effective Date of this Agreement, or 30 days after the previously suspended distribution center re-commences distribution of controlled substances, DEA shall conduct reviews of the functionality of Cardinal's diversion compliance program ("Compliance Reviews") at up to seven Cardinal

distribution centers, consisting of the Auburn Facility; the Lakeland Facility; the Stafford Facility; the Swedesboro facility; and two other Cardinal distribution centers selected by DEA, as well as the Controlled Substance Anti-Diversion investigatory files and processes maintained at Cardinal's Dublin, Ohio headquarters. DEA shall also review the investigatory files maintained by Cardinal of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify Cardinal no less than 48 hours prior to commencing a Compliance Review at a distribution center or at Cardinal's Dublin, Ohio headquarters. DEA shall issue a Notice of Inspection to Cardinal upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, Cardinal shall provide DEA with information in a form reasonably agreed to related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate Cardinal representative to provide DEA's preliminary conclusions regarding the Compliance Review. The parties agree that, at Cardinal's option, Cardinal may be represented by counsel at such Compliance Reviews and that DEA shall neither object to nor limit the number of counsel present at such Compliance Reviews.

d. The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to Cardinal on or before 165 days from the Effective Date of Agreement, stating that Cardinal failed to meet any of the requirements in either subsections II(2)(d)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with Cardinal within 48 hours regarding such a finding. DEA shall consider remedial measures that Cardinal has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

e. DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix F.

f. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA

shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

g. DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to September 30, 2008, which may allege that Cardinal failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by Cardinal to DEA on or before September 30, 2008, for indications that Cardinal may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix F, Paragraph 8) occurring before September 30, 2008, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

h. DEA represents that upon execution of this Agreement, Cardinal's pending application for renewals of the controlled substance registrations of the Auburn, Swedesboro, Lakeland, and Stafford facilities will be granted.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Auburn, Lakeland, Swedesboro, and Stafford facilities.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders to Show Cause and this Agreement; and

b. Refrain from filing any administrative claims against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of September 30, 2008, and the review of the reports and records Cardinal submitted to DEA prior to September 30, 2008.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further,

nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Cardinal's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than

those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to paragraphs II(2)(c) and (d) of this Agreement to Cardinal shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Mark Hartman, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614 757 6597; email: mark.hartman@cardinalhealth.com;
b. With copy to: Steve Falk, General Counsel – HSCS, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614 757 5051; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

Kerry Clark
Chairman and Chief Executive Officer

Dated:

Ivan Fong
Chief Legal Officer and Secretary

Dated:

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated:

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated: 9/26/08

FOR Wendy H. Goggin
Chief Counsel

Dated: 10/2/08

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

Dated: 9/30/2008

Ivan K. Fong
Chief Legal Officer and Secretary

Dated: Sept. 30, 2008

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated: 09-30-08

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated: 9/30/08

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated:

Wendy H. Goggin
Chief Counsel

Dated:

APPENDIX A

APPENDIX A

(Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (Specialty Pharmaceutical).

5. 2512 West Cott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 500 Jerry Steele Lane, McDonough, Georgia, operating under DEA registration number RC0271267.

7. 14601 County Road 212, Findlay, Ohio, operating under DEA registration number RC0313940.

8. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

9. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

10. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

11. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (Specialty Pharmaceutical).

12. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

13. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

14. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

15. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

16. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

17. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

18. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

19. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

20. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

21. 4 Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

22. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW0263056.

23. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

24. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

25. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

26. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

27. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (Parmed Pharmaceuticals).

APPENDIX B

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

NOV 28 2007

IN THE MATTER OF

Cardinal Health
801 C Street NW, Suite B
Auburn, Washington 98001

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RW0191813, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0191813 is assigned to Cardinal Health's Auburn, Washington, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on January 28, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0191813 at 801 C Street NW, Suite B, Auburn, Washington 98001. DEA number RW0191813 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

a. Respondent's largest purchaser of combination hydrocodone products in 2007, Horen's Drugstore, Inc. ("Horen's Drugstore"), is a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical

purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

b. Despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies such as Horen's Drugstore, and despite the public information readily available to Respondent regarding Horen's Drugstore's association with rogue Internet pharmacy websites, Respondent repeatedly supplied Horen's Drugstore with excessive amounts of hydrocodone. Specifically, Respondent distributed in excess of 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007; including over 116,000 dosage units in July; over 129,000 dosage units in August; and over 122,000 dosage units in September.

c. Respondent, disregarding the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances, distributed unusually large amounts of hydrocodone to Horen's Drugstore. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0191813 is hereby suspended, effective December 3, 2007, at 12:00 p.m. Pacific Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for January 28, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 11/28/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date _____ Time _____ Diversion Investigator _____

APPENDIX C

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

DEC 0 5 2007

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RC0182080, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RC0182080 is assigned to Cardinal Health's Lakeland, Florida, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 9, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA number RC0182080 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From August 2005 through October 2007, Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

3. Many of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

a. Retail pharmacies in Florida order an average of less than 8,400 dosage units of hydrocodone per month. Respondent distributed hydrocodone to pharmacies engaged in the diversion of controlled substances as reflected in the chart below. Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.

Pharmacy	Total Dosage Units	Number of Months Distributions Made	Monthly Average	Dates of Distribution (*Distributions not made in every month)
Medipharm-Rx, Inc.	620,030	4	155,007	Aug – Dec 05*
DRM Enterprises, Inc.	929,600	22	42,254	Jan 06 – Oct 07
Jen-Mar Pharmacy Services, Inc.	353,700	11	32,154 1st 3 mos: 2,766 Last 8 mos: 43,175	Mar 06 – Feb 07*
Armenia Pharmacy, Inc.	132,900	12	11,075 1st 6 mos: 1,900 Last 6 mos: 20,250	Mar 06 – Feb 07
National Pharmacy, Inc.	659,800	9	73,311	Aug 05 – May 06*
Parulmed Corporation	468,400	20	23,420	Aug 05 – Apr 07*
Q-R-G, Inc.	1,213,200	5	242,640	Feb – June 06
RKR Holdings, Inc.	741,000	13	57,000	Aug 05 – Jan 07*
United Prescription Services, Inc.	1,148,100	4	287,025	Jul – Oct 06
Satellite Drug and Pharmacy	1,044,000	19	54,947 1st 4 mos: 375 Last 15 mos: 69,500	Feb 06 – Oct 07*

b. Respondent distributed hydrocodone to the pharmacies identified in subparagraph 3.a, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from the

Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

c. Respondent distributed hydrocodone to each of the pharmacies named in subparagraph 3.a, above, and to other pharmacies engaged in Internet diversion schemes, in amounts that far exceeded the legitimate needs of its customers.

d. On September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for the Respondent, sent an email to DEA's E-Commerce Section stating that the Respondent had discontinued its sales of controlled substances to 13 suspected Internet pharmacies. Included in Respondent's report of discontinued accounts was the aforementioned RKR Holdings, Inc. ("RKR"). On that same date, Respondent distributed 200 dosage units of combination hydrocodone products to RKR. From September 1, 2006, to January 31, 2007, Respondent distributed 393,600 dosage units of combination hydrocodone products to RKR.

4. Respondent repeatedly supplied the pharmacies named in paragraph 3.a, above, and other pharmacies, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers' association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective December 10, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 9, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/5/07
Michele M. Leonhart
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

_____ _____ _____
Date Time Diversion Investigator